esaote

Doc # : 29B41SM02

Service Manual

MyLab™40

MyLab™20Plus

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1 INTRODUCTION

1.1 The MyLab40/MyLab20Plus

The MyLab40/MyLab20Plus is a console ultrasound system with a 19 “LCD. The console contains: the electronics, the control panel with speakers, the probe connectors, the input/output connectors for the ECG, the roll base (including brakes on the front wheels), a space to hold peripheral units (video recorder, video printer, and additional accessories), and main switch. The console has a handle on the back.

1.2 Warning and precautions

Please refer to the Safety and Standard manual. This manual can be found on the user manual CD.
The document numbers are as follows:

English	29B05ENxx
German	29B05DUxx
French	29B05FRxx
Spanish	29B05SPxx
Italian	29B05ITxx

1.3 Specifications

Display

- 19” LCD, TFT technology, color XVGA

Probe connectors

- 3 electronic probes
- 1 Doppler probe

Video I/O

- XVGA (monitor)
- S-VHS I/O
- VHS I/O
- RGB (TV standard)
- Video standard
- PAL / NTSC

Connectivity

- I/Os connectors
  - LAN RJ45
  - 2 USB
- Dedicated connectors
  - ECG input
  - Foot switch
- Other
  - Laser/Ink jet printers
- Complies with IHE integration profiles

Image Files

- Formats
  - Standard output file formats (BMP, AVI)
  - Native and Dicom formats
- Clips characteristics
  - AVI Codec: Microsoft MPEG-4 V2
  - Compression: JPEG lossy compression (about 70% of quality)
- Still frames / BMPs are stored at full resolution

Software

- Operating system: WIN XP Embedded
- Multi-lingual

Biometry

- Basic and advanced calculation, application dependent
- Annotations, bodymarks

Keyboard

- Echografic
  - Potentiometers for TGC
  - Encoders for general gains
  - Keys for modes, peripherals management and controls

Dimensions

- 135 (H) x 54 (W) x 80 (D) cm

Weight

- About 60 kg

Power Supply

- Voltage operative range:
  - 100 ÷ 120V
  - 200 ÷ 240 V
- Mains frequency: 50 ÷ 60 Hz
- Power consumption: ≤ 600 VA
- Available power for peripheral units: up to 600 VA
- Auxiliary power plugs: 4 insulated

Operating requirements

- Temperature: 15÷35 ºC
- Humidity: 15÷95 % (not condensing)
- Pressure: 700÷1060 hPa

Storage requirements

- Temperature: -20 ÷ +60ºC
- Humidity: 5÷95 % (not condensing)
- Pressure: 70÷1060 hPa

Safety Standards

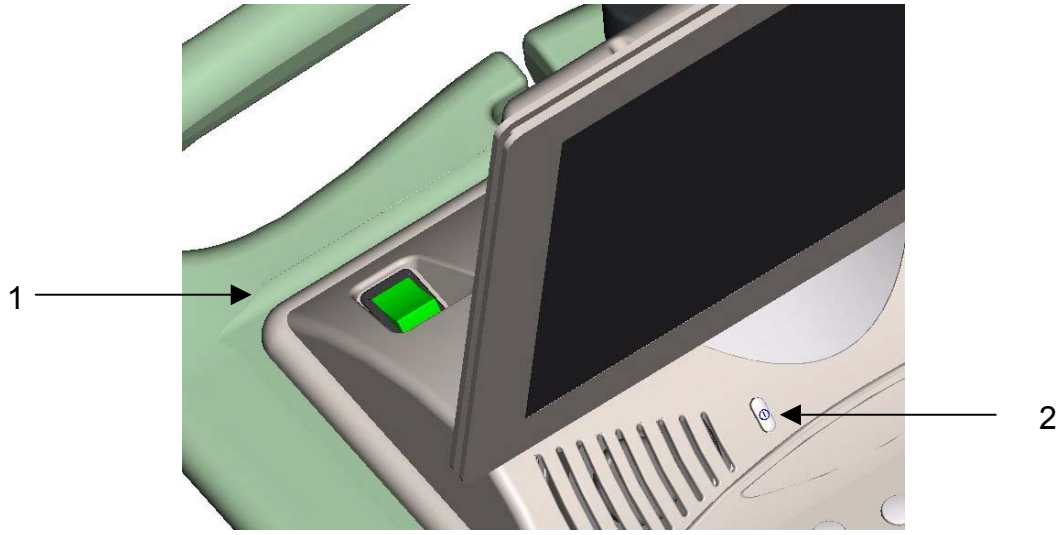
- EN 60601-1
- EN 60601-1-1
- EN 60601-1-2
- EN 60601-1-4
- EN ISO 10993-1
- EN 60601-2-37
- EN 61157
- AIUM / NEMA UD-2 / UD-3 – FDA 510(k) Track 3

NOTE
Specifications may change without prior notice.

2 INSTALLATION

The MyLab40/MyLab20Plus has two switches: a power switch and a shutdown switch.
The power switch is located at the rear side of the keyboard of the system and supplies both the system and the connected peripherals with power. The shutdown button is located between the two speakers on the keyboard, accessible from the front, and starts/shuts down the system.

NOTE
The shutdown button is active only if the power switch is on.



The table below lists the switches and their intended use.

Reference	Switch	Use
1	Power switch	Connect mains to scanner and peripherals
2	Shutdown button	Shuts down the scanner

With the exception of the probes, all connectors are located on the rear panel of the console. The connectors are all clearly identified according to the type of peripheral unit for which they are intended.

LCD screen

The LCD screen can be installed with cabling inside or outside the LCD support spine cover. The easiest way is outside cabling.
Requisites: Mounting set LCD, containing:
2 x M5*16 socket head button screw,
4 x M4*12 socket head cap screw,
3 x M3*10 socket head countersunk screw,
Allan keys 2mm and 3mm.

Installation with cabling inside spine cover

- Remove PCB rack from the console.
- Attach hinge to LCD screen using 4 x M4*12 head cap screw. (See figure 1)
- Attach LCD screen support to the console with 2 x M5*16 socket head button screw. (Rotation limit pawl facing backside of the console, see figure 2.)
- Lead the power cord and DVI signal cable through the console and spine cover.
- Place the cover over the spine.
- Position the LCD with hinge on the support spine and fix it using 3 x M3*10 socket head countersunk screw. (See figure 4)
- Plug in the mains supply connector and DVI signal cable. (See figure 3)
- Reinstall the PCB rack, connect the video connector to C1 and plug the power cord in one of the outlets of the socket panel (J1 – J4). (See Electrical connections)

Figure 1

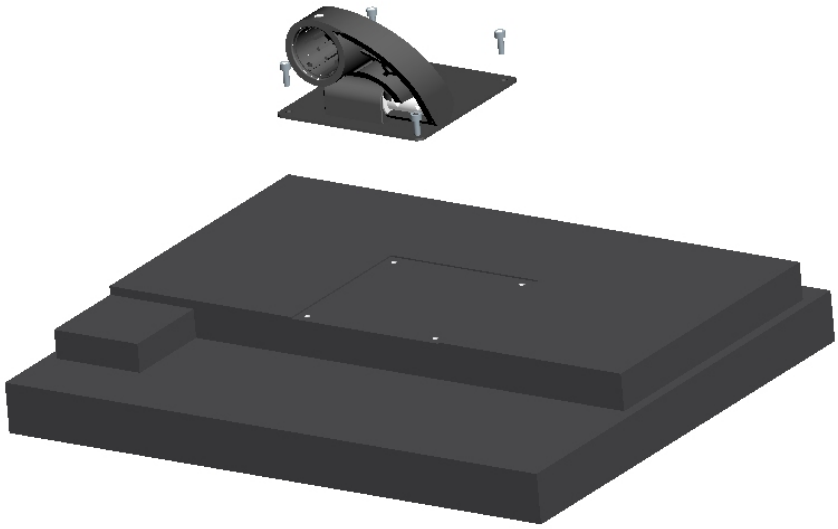


Figure 2

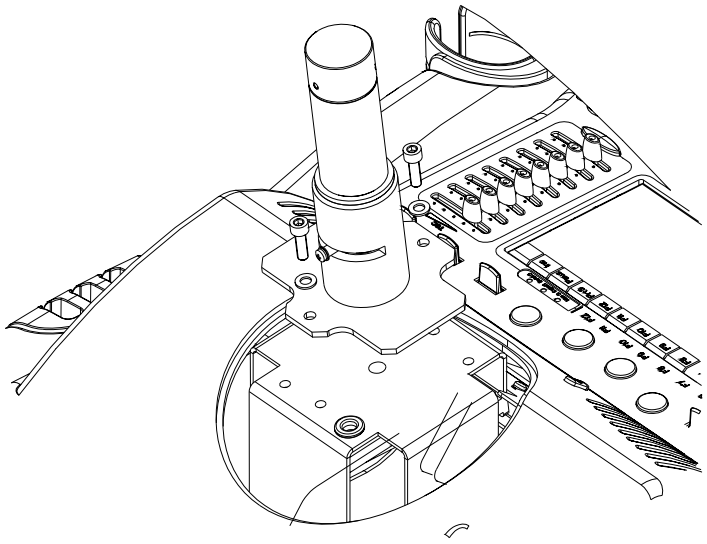


Figure 3

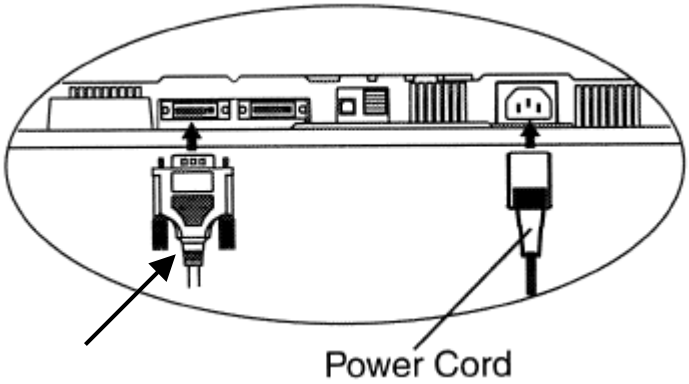
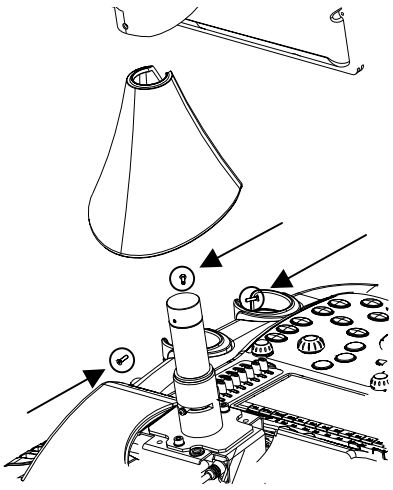


Figure 4

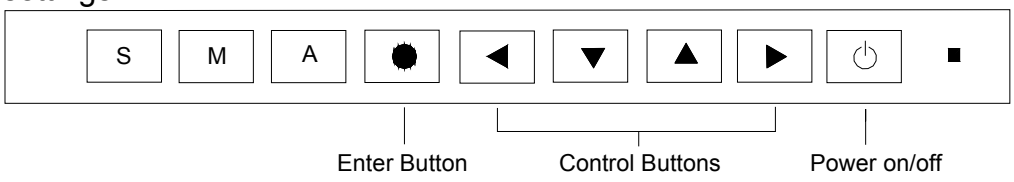


Installation with cabling outside the spine cover:

- Attach hinge to LCD screen using 4 x M4*12 head cap screw. (See figure 1)
- Attach LCD screen support to the console (rotation limit pawl facing backside of the console, see figure 2.)
- Place the cover over the spine.
- Position the LCD (with hinge) on the support spine and fix it using 3 x M3*10 socket head countersunk screw. (See figure 4)
- Plug in the mains supply connector and DVI signal cable to the LCD screen.
- (See figure 3) Connect other end of the DVI signal cable to the SVGA connector C1. (See Electrical connections) and plug the power cord in one of the outlets of the socket panel (J1 – J4). (See Electrical connections)

LCD settings

The monitor left the factory calibrated but eventually the brightness and contrast settings can be adjusted to the environmental conditions. Press the up or down arrow to access the brightness/contrast menu. Highlight ‘brightness’ or ‘contrast’ by pressing the up or down arrow, press the left or right arrow to adjust. Press the enter button to save and leave the menu. It’s recommended not to change any other settings.



Menu settings LCD

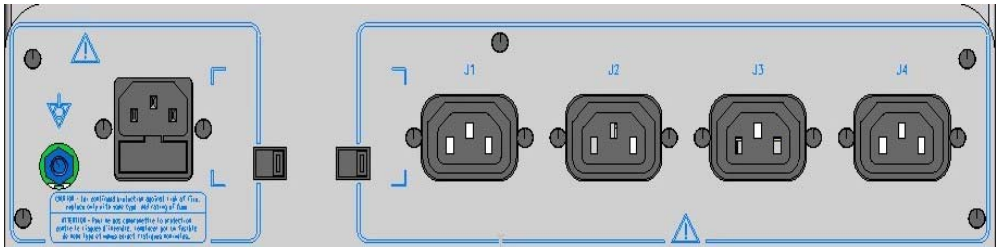
To optimize the performance of the LCD screen or CRT monitor, check the ‘video options’ menu settings. To enter this menu, press the Menu button, click on ‘System Setup’ and ‘Video options’ then select the type of display connected to the system.

LCD adjustment settings can be checked in 6.1 LCD screen settings on page 32.

Probes Connection

The probes can be indiscriminately connected to the 3 connectors. Probe connection procedure: make sure that the connector-securing device is in the "OPEN" position, align the pins of the two connectors and carefully fit the probe in the connector, turn the securing device to its "LOCK" position to secure the probe in the connector.

Socket panel



Use one of the additional power cables supplied with the system to power the MyLab15/20 from any of the sockets (indicated by symbols J1, J2, J3 and J4) in the socket panel. Plug in the power cable and connect the console to the power mains.

CAUTION
Do not exceed the maximum output power limit (600 VA) as indicated on the insulated sockets. There is a risk of blowing the system fuses.

CAUTION
Do not switch off the machine before initialization has finished. The MyLab15/20 can be switched off only when the start exam window is shown - this window is used to input the patient data and to choose the application.

WARNING
The base of the system has brakes on the front wheels, which can be individually operated.
Don’t park the system on inclined planes. Do not use the brakes to park the system on inclined planes.

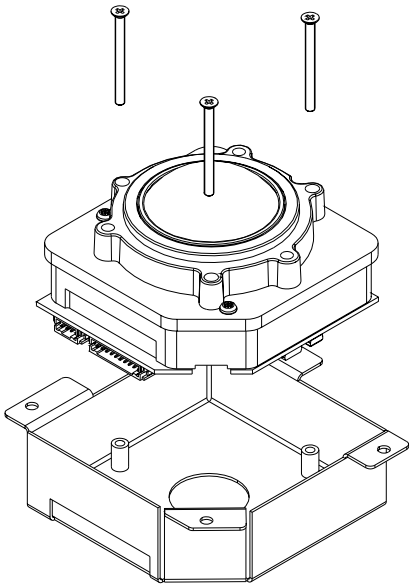
3 MAINTENANCE

3.1 Planned maintenance

3.1.1 Unit

Although the unit is produced with the utmost care and only the highest quality components are used, maintenance will be necessary from time to time to ensure trouble-free operation.

- Remove loose dust from the exterior with a soft cloth or a dry brush. A solution of water with a mild detergent may be used. Avoid aggressive cleaners.
- Check the ventilation fans of the unit for proper operation.
- Remove dust from PCB's and connectors. Consult section Unit disassembly on page 11 for disassembly instructions.
- Clean the track ball
- Remove at the lower side of the keyboard, the 3 screws that secure the cover plate.
- Detach the cables from the trackball.
- Remove the 2 screws that secure the trackball. Hold the track ball, as it may fall.
- Remove the 3 screws (M3 x 35) to remove the shielding.
- Remove the 3 screws to remove the trackball cover plate.
- Clean the track ball and rods.



3.1.2 Probes

Please refer to the Transducers and Consumables manual. This manual can be found on the user manual CD and protected web.
The document numbers are as follows:

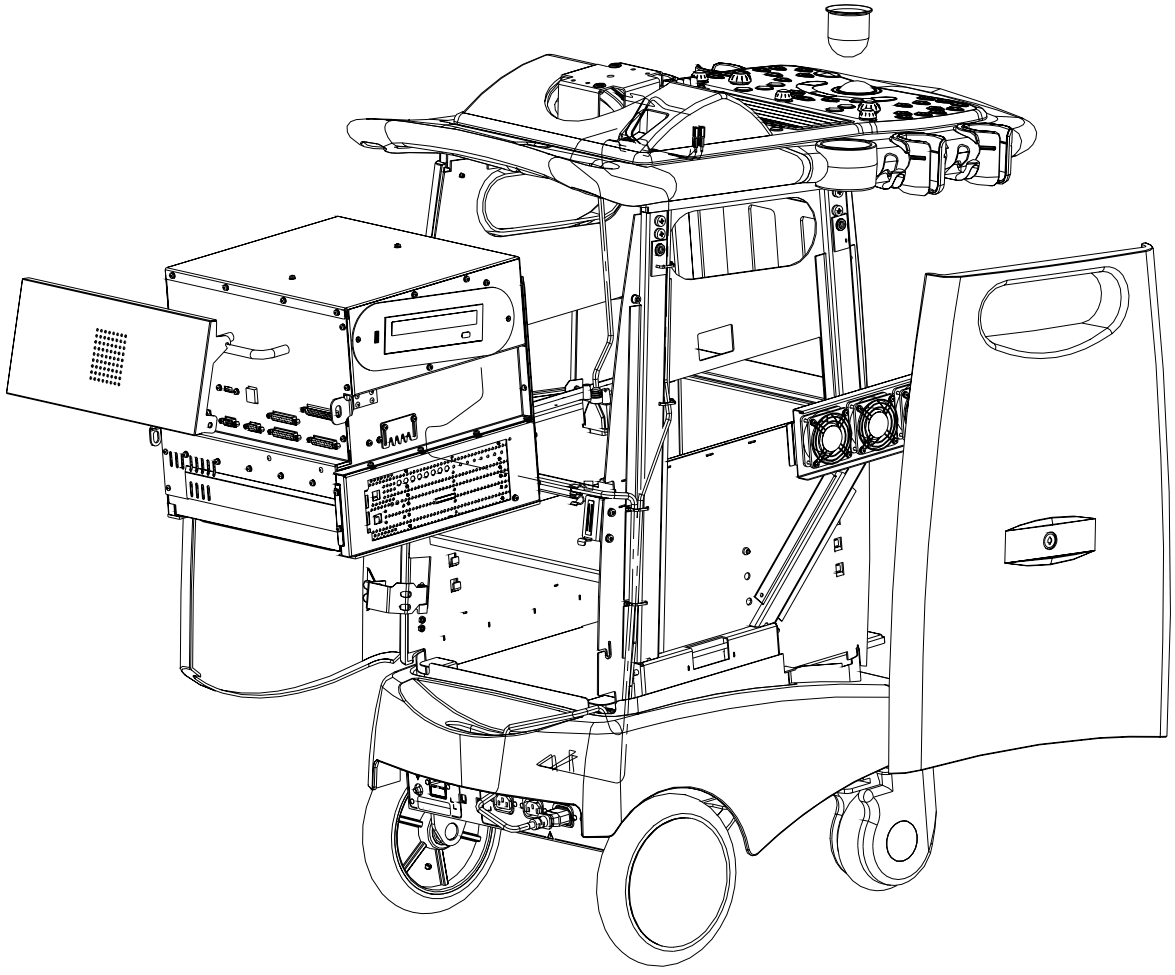
English	29B04ENxx
German	29B04DUxx
French	29B04FRxx
Spanish	29B04SPxx
Italian	29B04ITxx

3.2 Unit disassembly

Make sure that the mains cable is disconnected from the mains before opening the system.

3.3 PCB rack removal

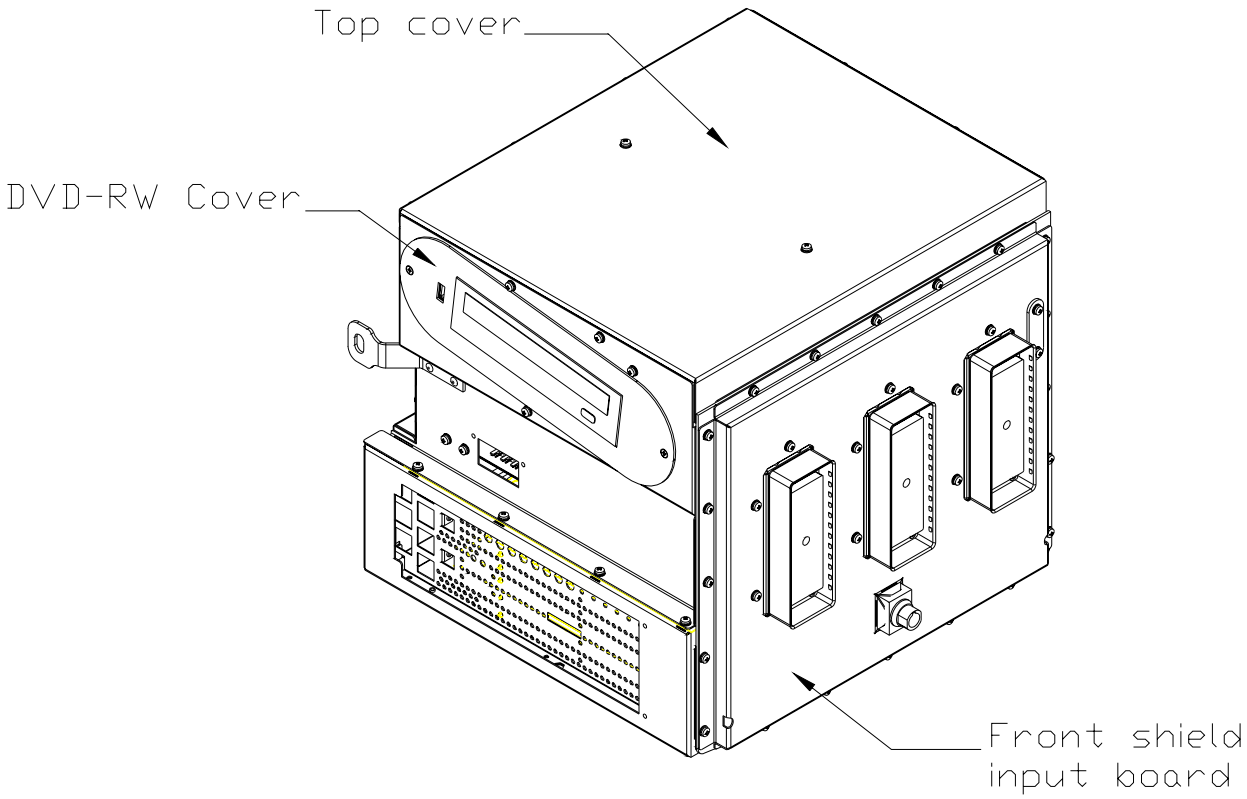
Detach all probes, cables and USB memory drives from the unit.
Remove the gel holder.
Remove the left and right side panel.
Detach the fan power cables, located at the left side of the trolley, from the PCB rack. (Slide the white cover slightly upwards to access the connectors).
Remove the fan assembly.
Detach the mains cable from the pcb rack, located at the other side as the fans.
Remove the plate that covers the pcb rack.
Remove the screws that secure the PCB rack and gently slide the pcb rack out of the trolley.



3.4 PCB rack disassembly

NOTE
When powering up the PCB rack for testing, make sure the fans are placed to provide cooling. The system will overheat in case the fans or not placed.

Remove the top cover from the pcb rack (14 screws)



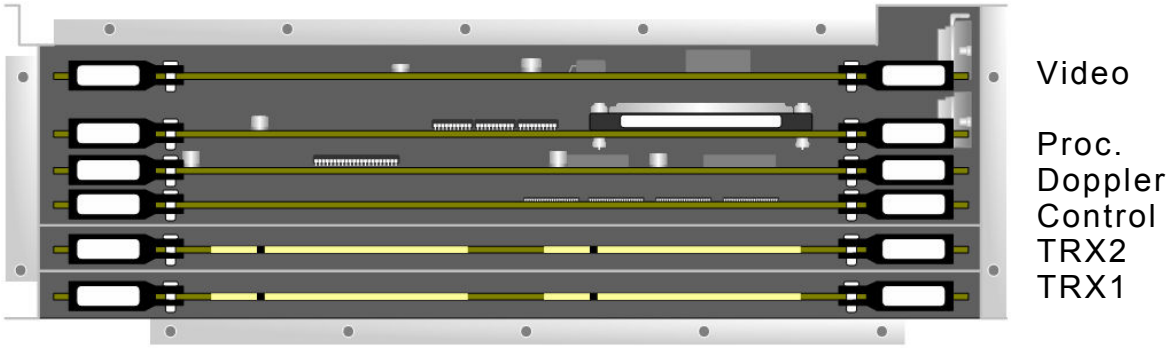
3.4.1 DVD-RW drive removal

Remove the DVD-RW cover plate.
Detach the power and data cable from the DVR-RW drive.
Remove the screws that secure the DVD-RW assembly and remove the DVD-RW drive.

3.4.2 PCB removal

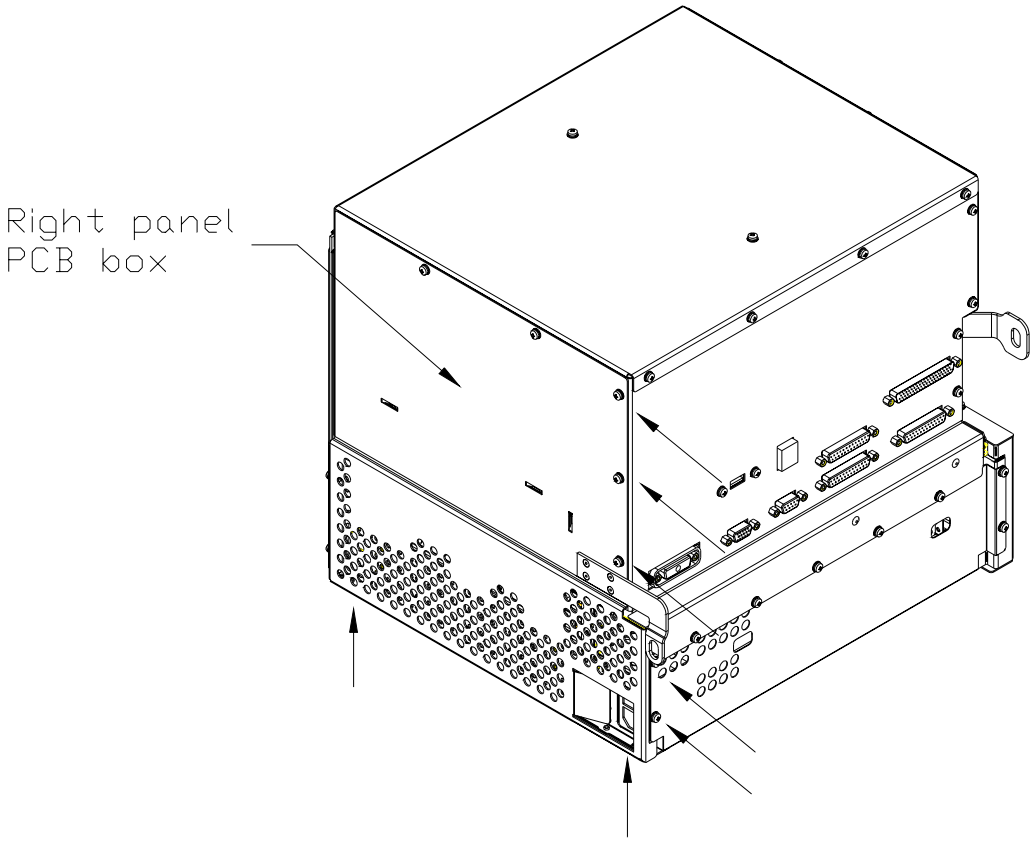
Remove the Front shield Input board (28 x M3 and 5 x M3 recessed).
Remove the 5 screws that fix the input board.
Remove carefully the input board.

Now the TRX1, TRX2, Control and Doppler board can be removed.



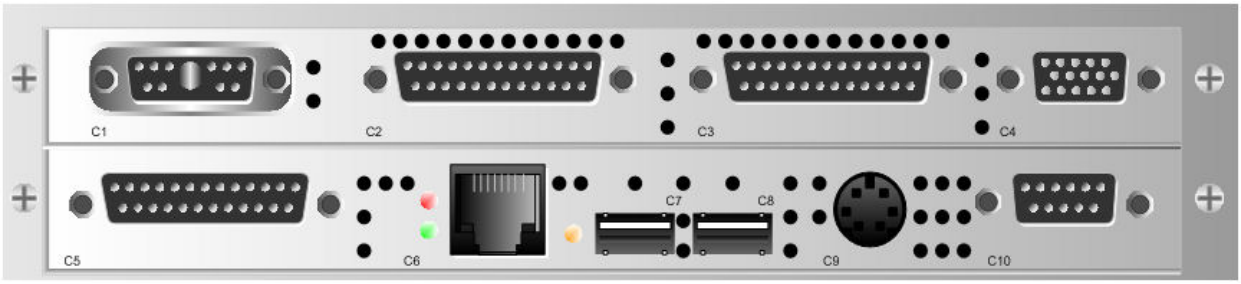
Video board and Processor board

Remove the right panel PCB box (7 screws)

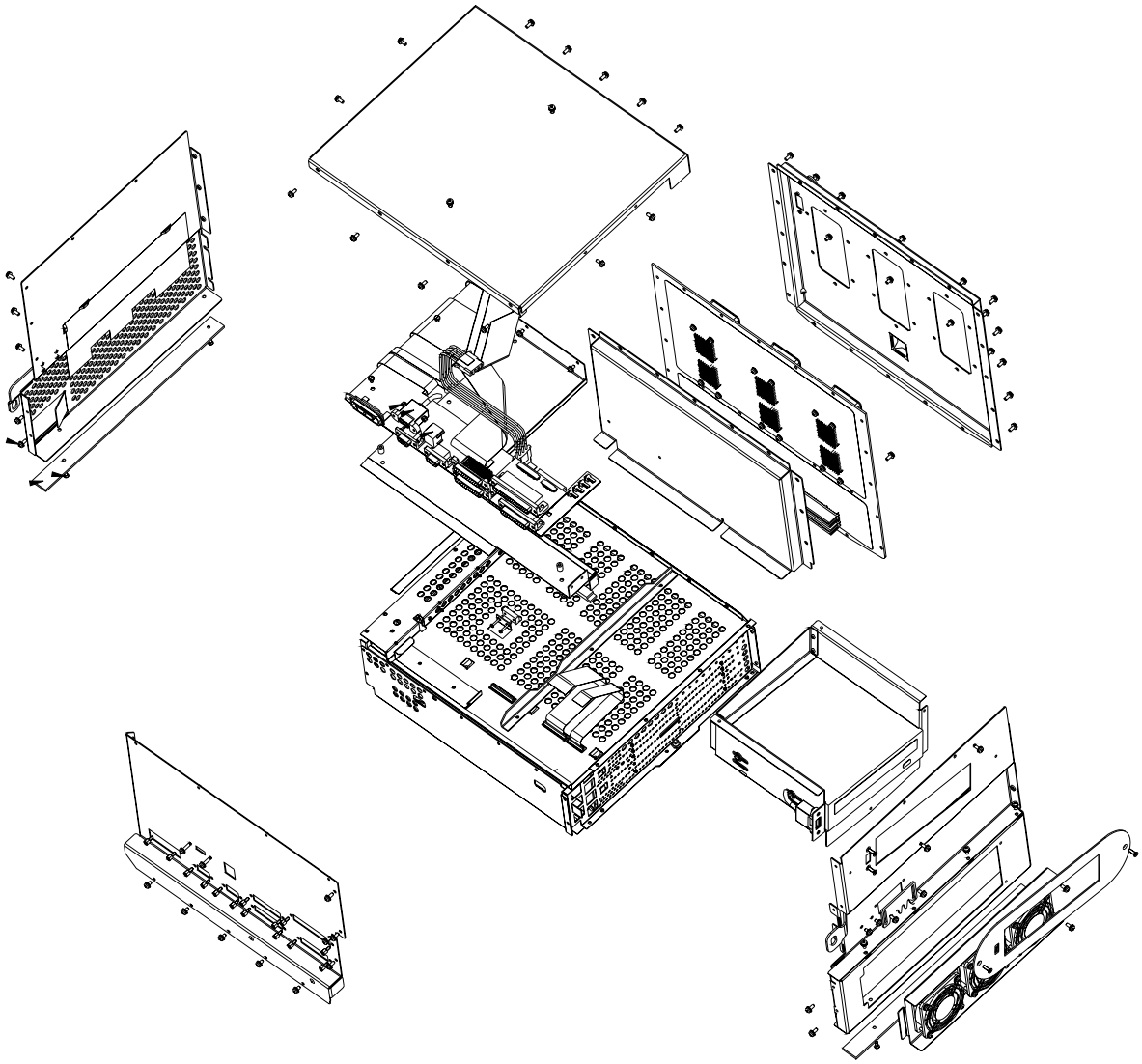


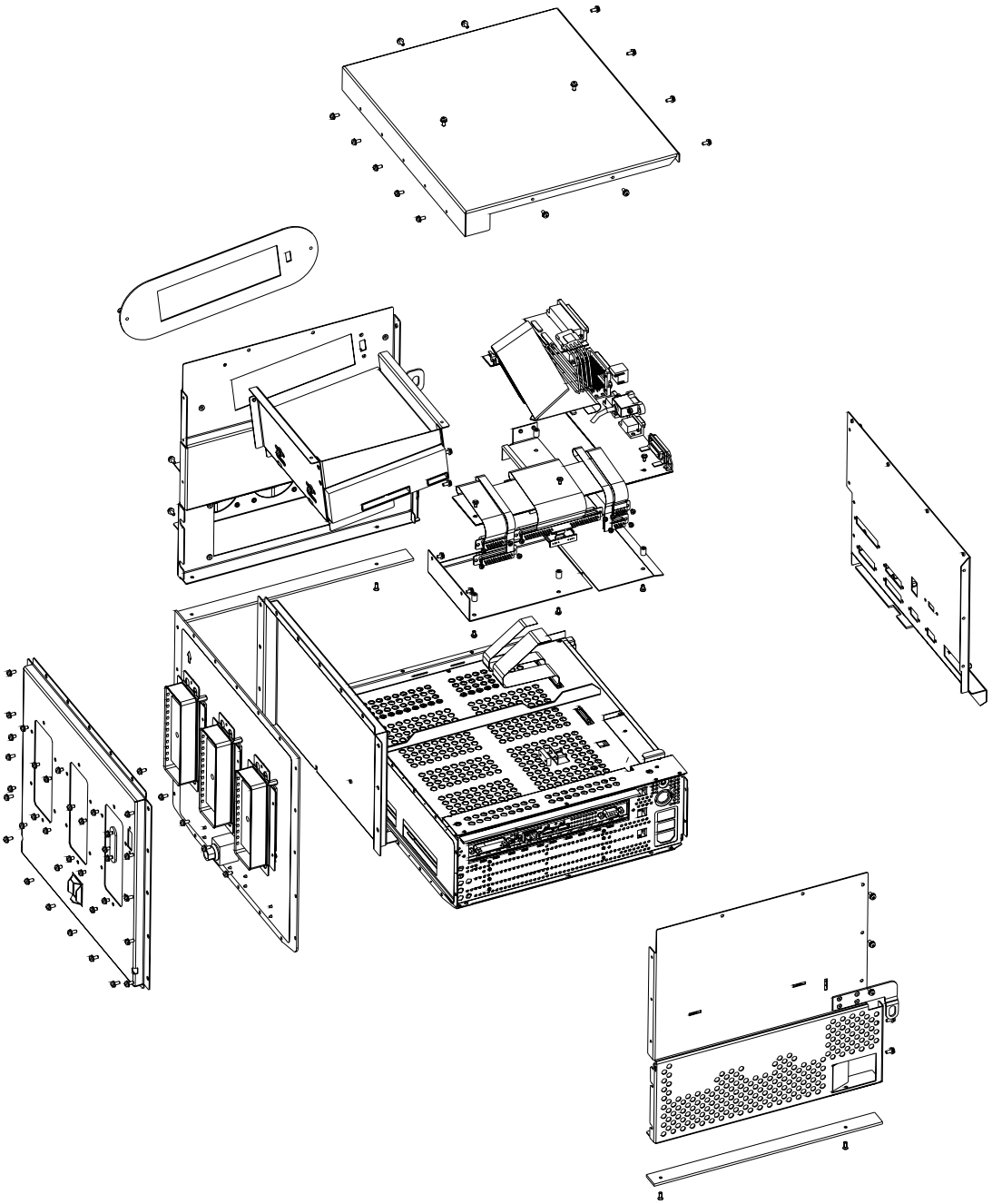
Detach the connectors coming from the I/O board from the video board and remove the 2 screws to remove the video board.

Detach the connectors coming from the I/O board from the processor board and remove the 2 screws to remove the video board.



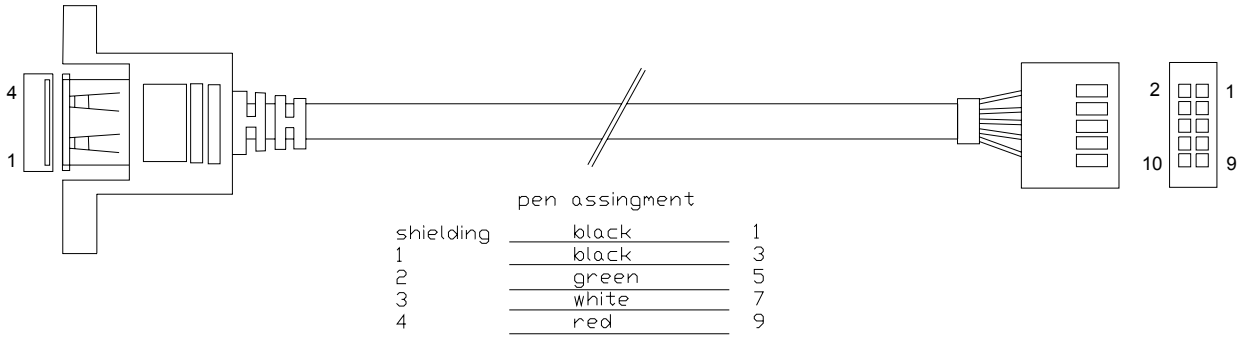
3.5 Exploded view PCB rack



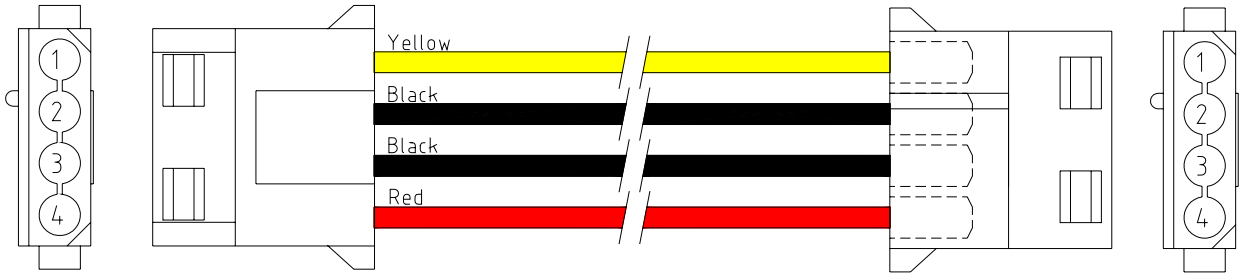


3.6 Cable drawings

3.6.1 USB cable internal

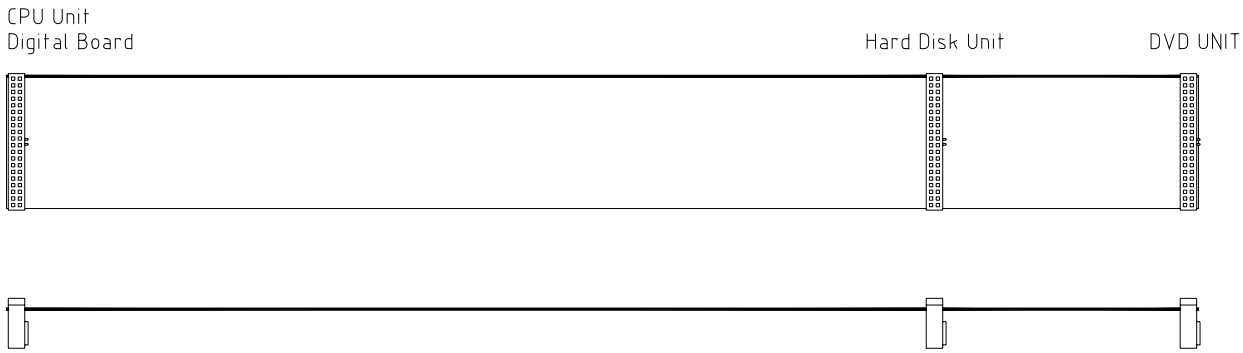


3.6.2 DVD power cable



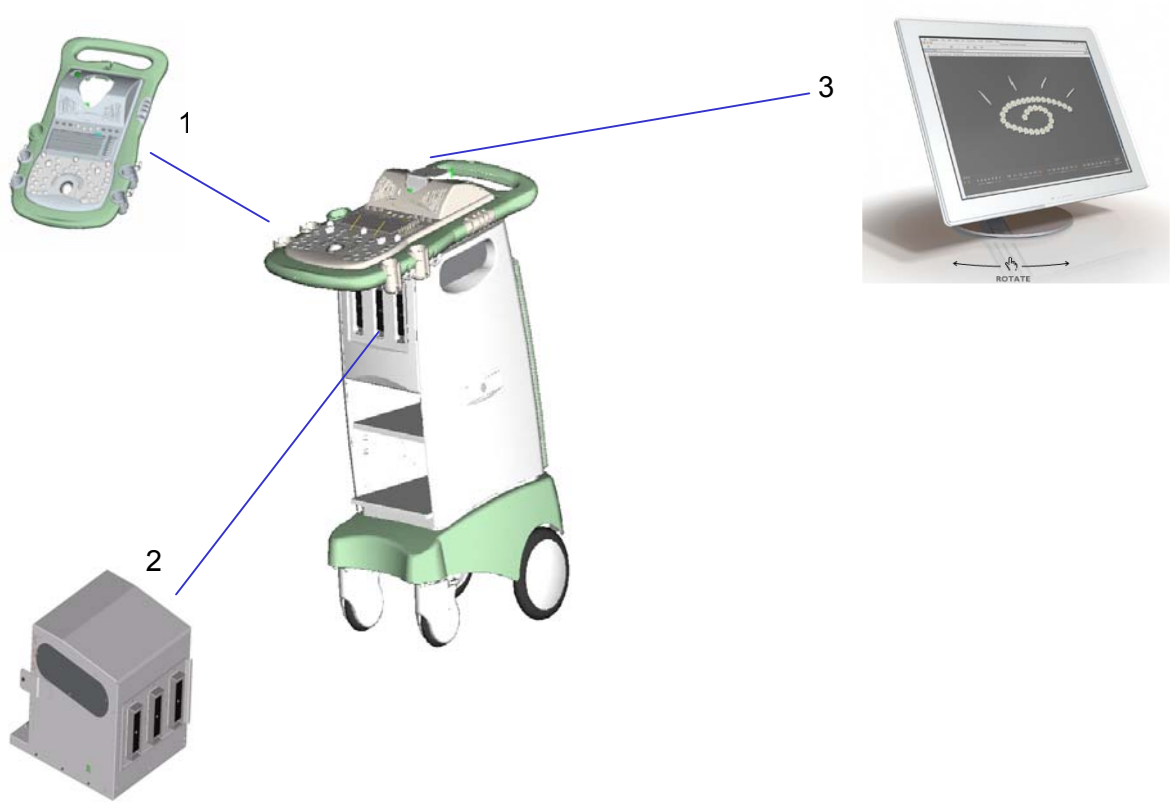
3.6.3 I/O board power cable

3.6.4 CPU <> HD/DVD unit



3.7 Parts list

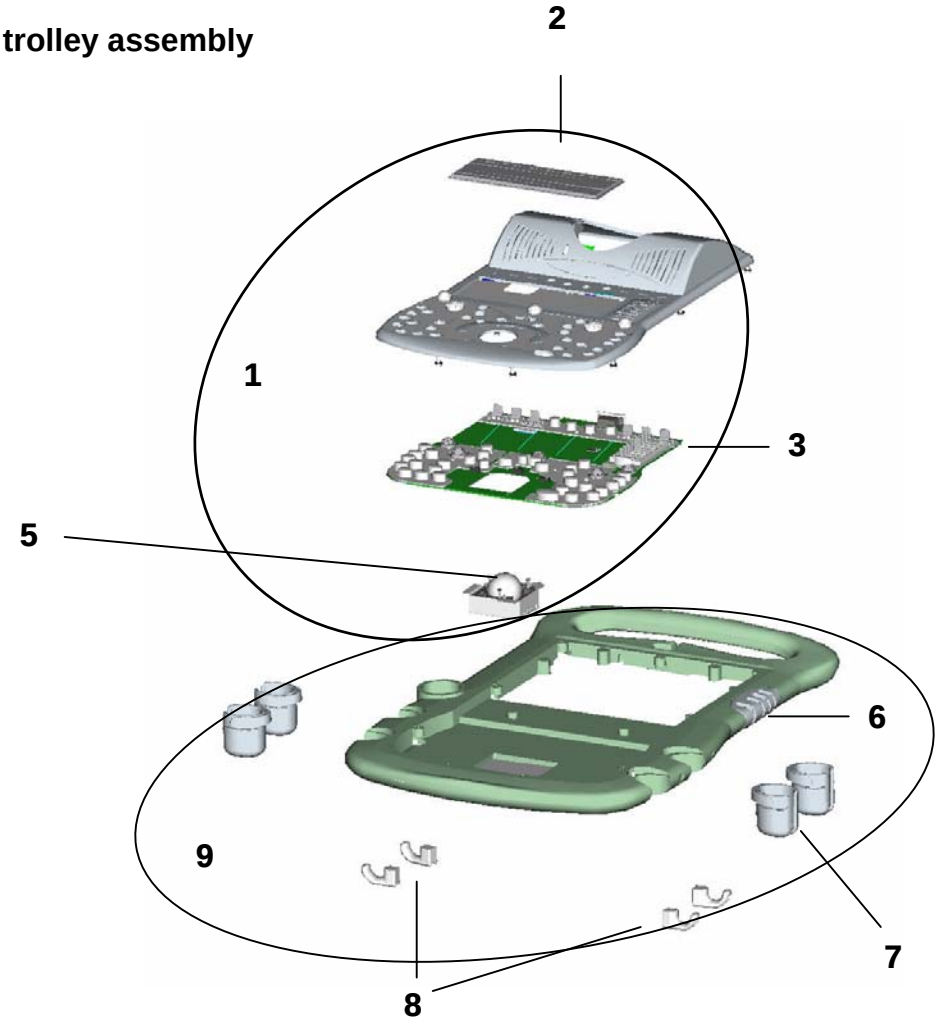
3.7.1 Main parts



	Description	*Board number*	*Service parts*
1	Top trolley assembly	312511	97154 712304
2	PCB-rack MyLab40/MyLab20Plus	312509	97154 712305*
3	LCD L788 19" Monitor	n/a	97154 411302

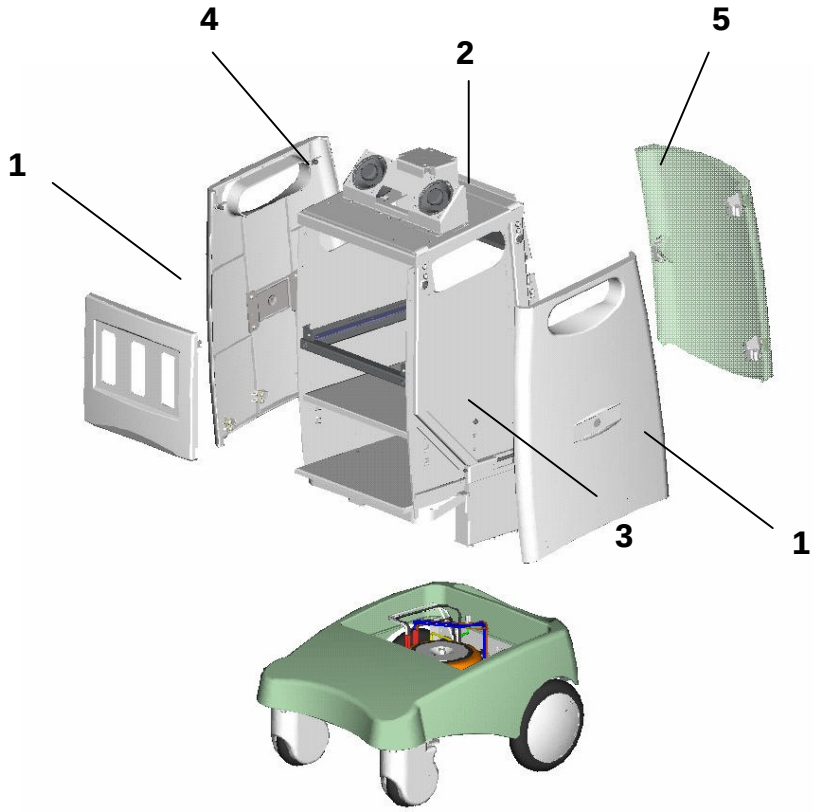
*** PCB rack – Serial number of the unit needs to be installed in factory before actual shipment**

3.7.2 Top trolley assembly



	Description	*Board number*	*Service parts*
1	Upper housing keyboard incl. keyboard	312512	97154 712306
2	Alphanumeric keyboard	9730640009	97154 711539
3	Keyboard including silicon parts	312580	97154 712308
5	Trackball assembly		97154 711541
6	ECG cable guide		97154 711542
7	Probe holder		97154 711543
8	Cable guide (4 pcs)		97154 711544
9	Base	311637	97154 711540

3.7.3 Base Trolley assembly



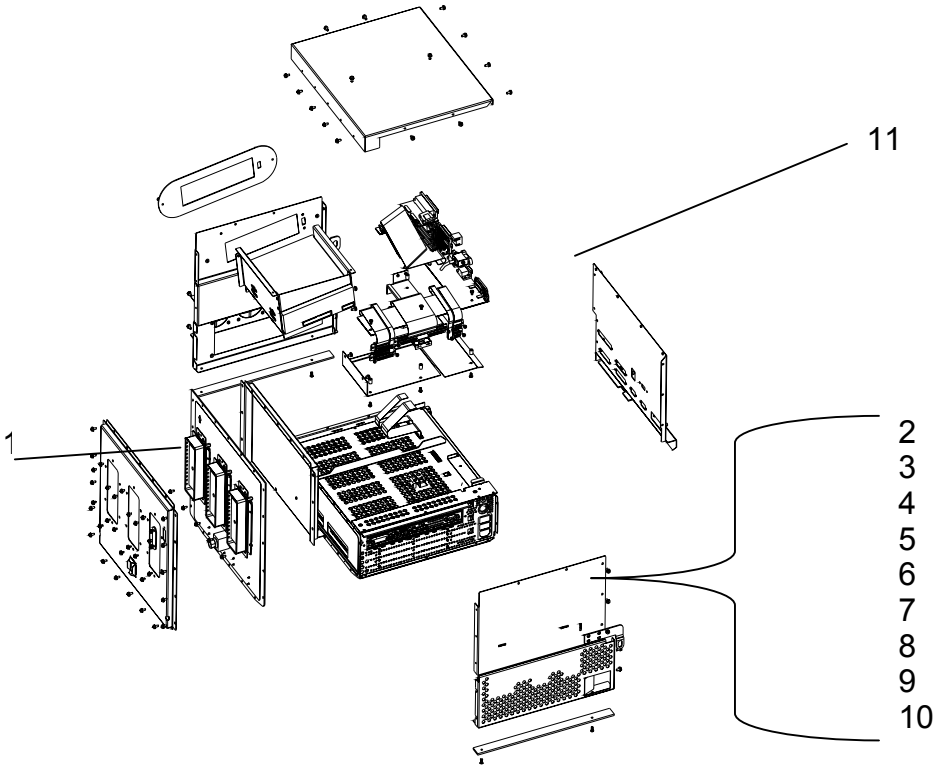
	Description	*Service parts*
1	Side panel assembly	97154 711547
2	Rear panel	97154 711548
3	Fan module rack	97154 712294
4	Speaker	97154 711550
5	Door Assembly	97154 711551

3

3.7.4 PCB rack

Identifying the boards
Most boards of the ML40 PCB rack are identified by:

- its Board number (950..) and serial number, which are always indicated on the external side of a pull tab.
- its Configuration Index (CI), indicated by two decimal figures or the revision letter, indicated on the backside of a pull tab. The Configuration Index represents the HW level of the board.
- and its description, also indicated on the backside of a pull tab.



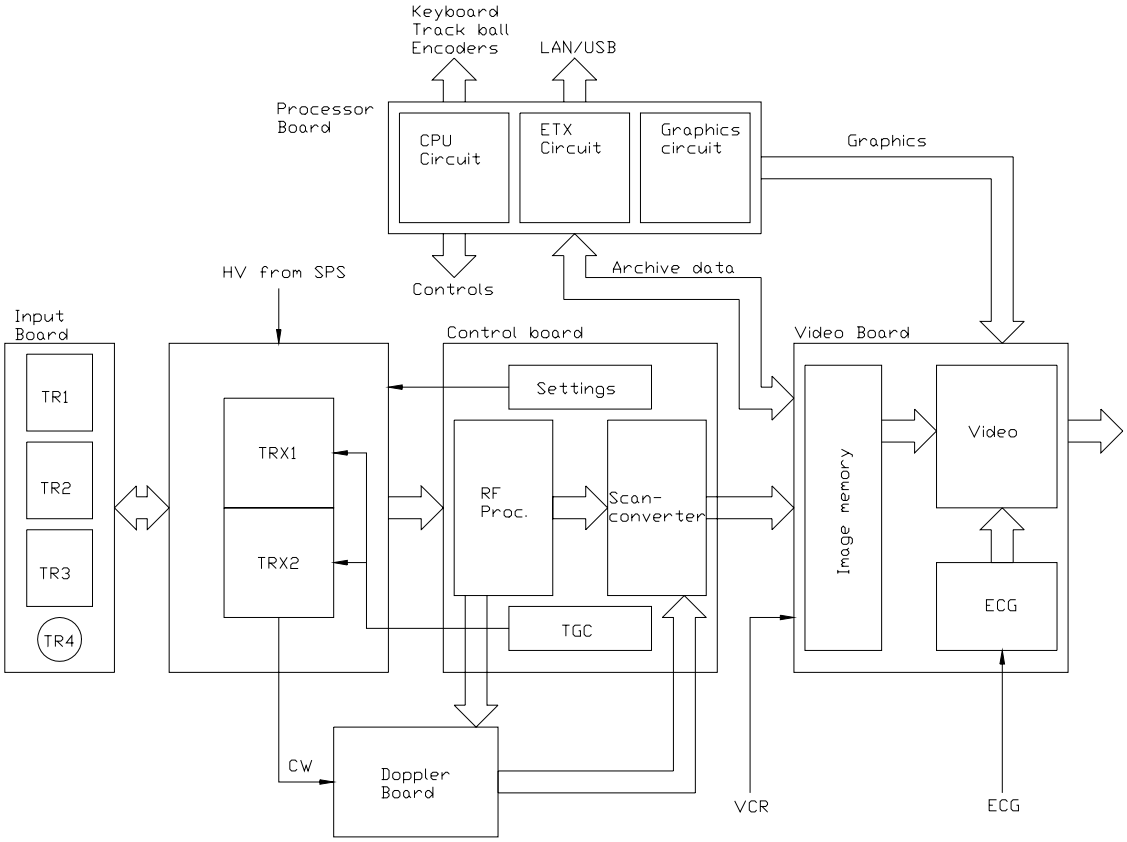
	Description	*Board number*	*Service parts*
1	Input board	312523	97154 712295
2	TRX1 board	9501076000	97154 712296
3	TRX2 board	9501077000	97154 712297
4	Control board (CI 12)	9501078010	97154 712298
5	Control board (CI 13)	9501078020	97154712333
6	Doppler board	9501079000	97154 712299
7	Processor board incl CPU and HDD (CI 14)	9501080010	97154 712300
8	Processor board incl CPU and HDD (CI 21/22)	9501080000	97154712322
9	Processor board incl CPU and HDD (CI 32)	9501361000	97154712357
10	Video board	9501081000	97154 712303
11	I/O Board assy	312700	97154 712301

4 EXPLANATIONS

The MyLab40/MyLab20Plus is built up with the following boards, each with its specific function:

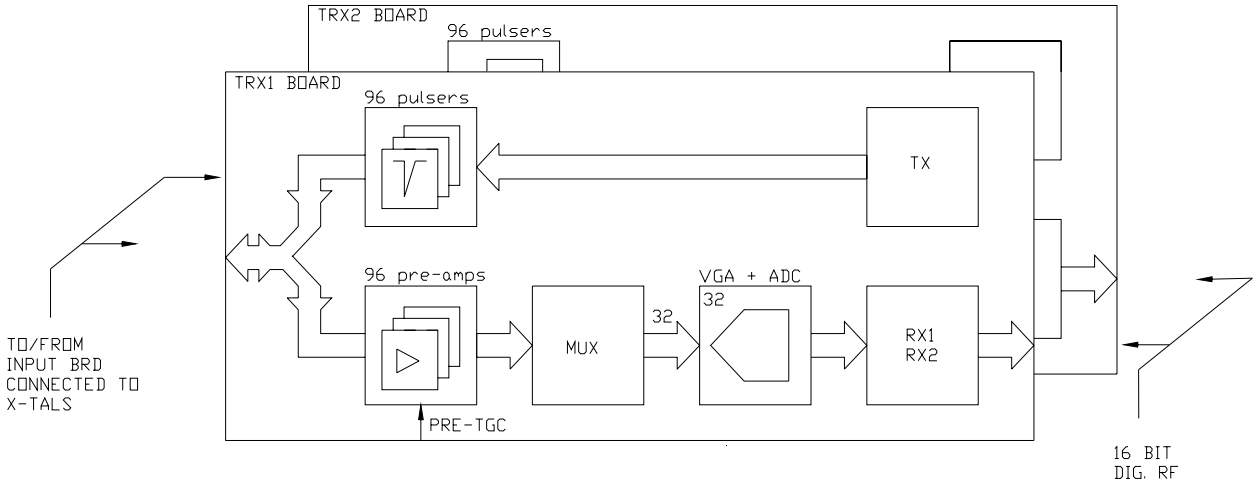
- Input board
- TRX1 and TRX2 board
- Control board
- Doppler board
- Video board
- Processor board
- Connector board
- Power supply
- Keyboard and TGC

4.1 General block diagram



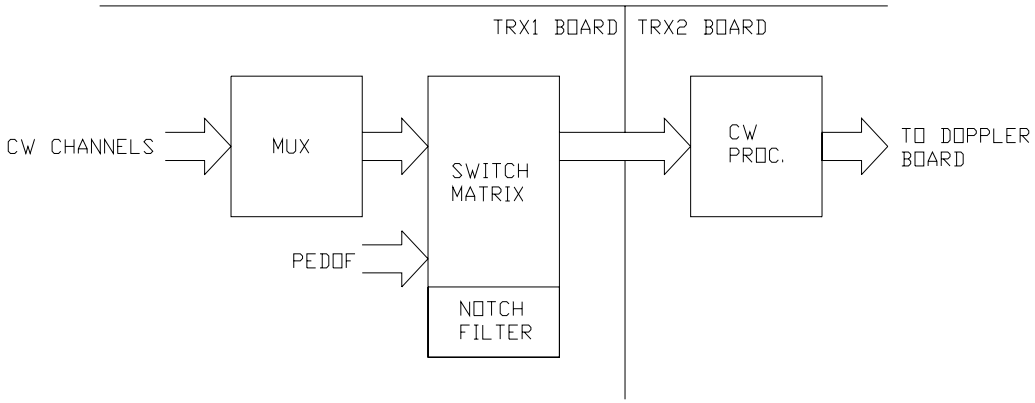
Input board
The probes are connected to the input board which has 3 probe connectors and one Doppler probe connector.
The input board switches the transmit and receive signals to and from the correct probe connectors to the TRX1and TRX2 board.
The probe identification is send to the control board.

TRX1 & TRX2 boards
The TRX1 and TRX2 manage the transmit and receive signals to and from the probe. Each board has 96 transmit and receive channels which enable the use of 192 element probes.
The pulsers generate the high voltage transmit pulses (HV coming from power supply).
The timing of the transmit pulses is controlled by the TX block and is done in such way that the transmit beam is focused.



The received signals are amplified by the pre-amps and after that the MUX switched the 96 inputs to 32 groups.
The Variable Gain Amplifier and ADC circuit amplify the signals with the user controlled gain curve and converts the signals into digital samples.
The digital samples are delayed, summed and filtered in the receive blocks RX1 and RX2 and forms the 16 bit digital RF signal.

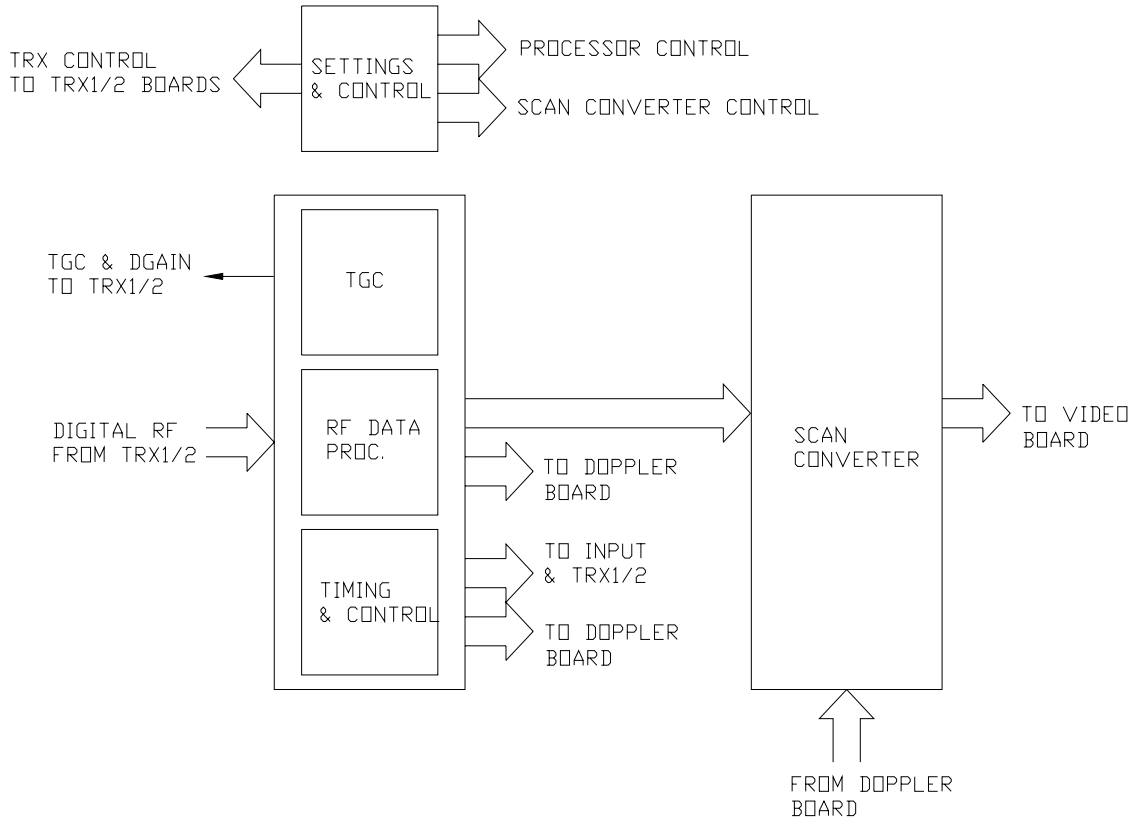
The TRX1 and TRX2 board are almost identical. The only difference is in the CW path.
In case CW is active the CW channels are switched from the MUX to the SWITCH MATRIX. The information from the Pedof probe is going directly to the SWITCH MATRIX.
The SWITCH MATRIX takes care of focusing the received information while the NOTCH FILTER eliminates the emitted Doppler frequency.
The information is then processed on the TRX2 board and going to the Doppler board.



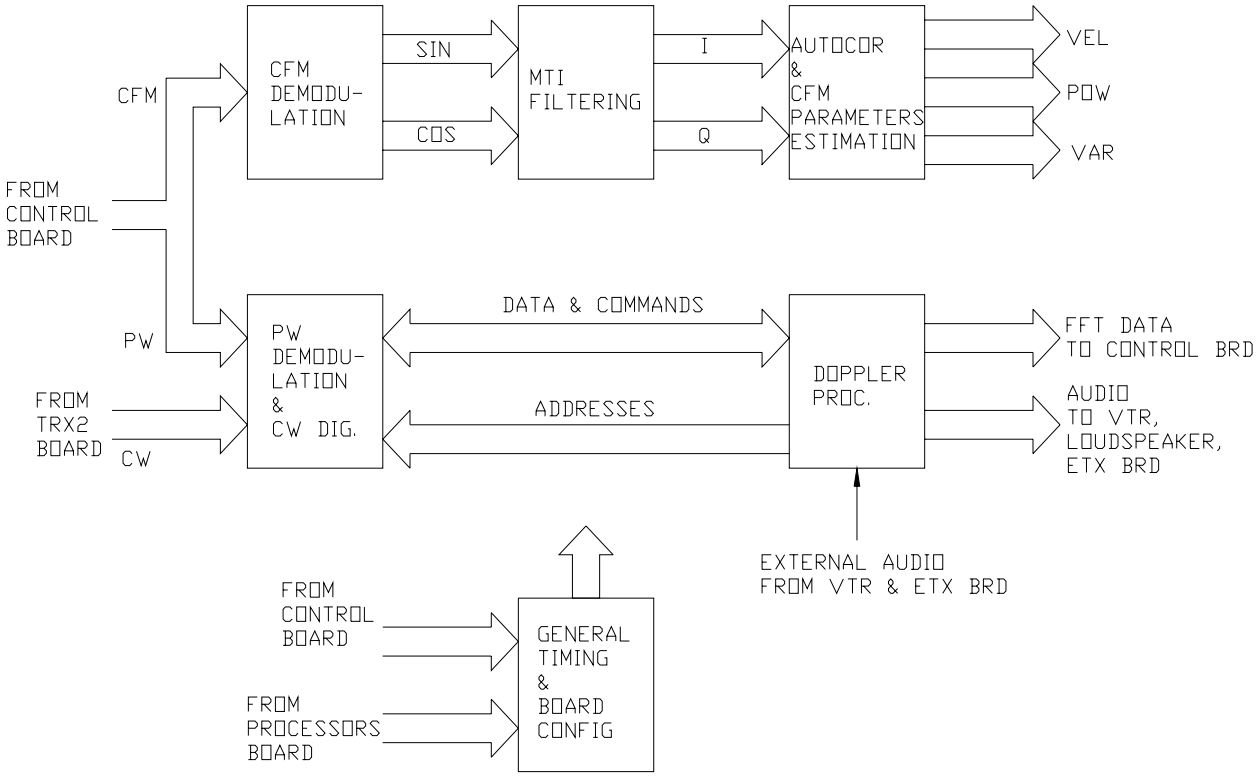
Control board
The control board has several functions.
It controls the timing transmit and receive sequences on the TRX1 and TRX2 boards and it provides the interface between the processor board and scanconverter which is located on the control board.

An other function is the processing of the Digital RF data.
The processed RF data is going to the scanconverter while the Doppler data is going to the Doppler board
The timing and control circuit is in control of several control signals such as the probe identification and probe selection and for Doppler controls such as PRF timing.

Also the TGC signals are generated which are used on the TRX1 and TRX2 boards.



Doppler board
The Doppler board receives the RF signal and extracts the Doppler information (CW, PW and CFM).
The PW and CFM signals are digital data coming from the Control board and the CW signal is coming from the TRX2 board in analog format.



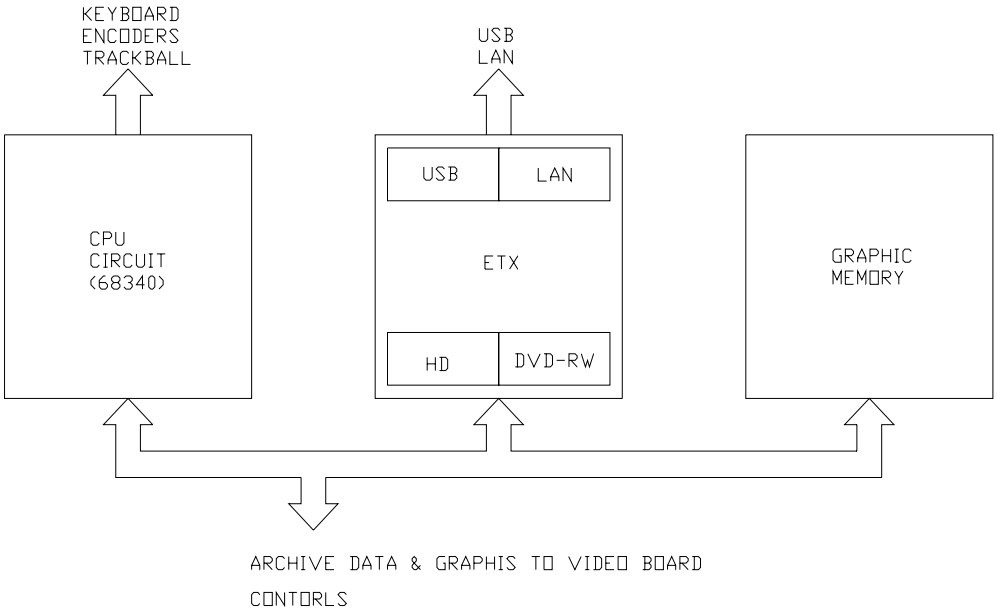
The CFM Demodulation circuit extracts from the RF signal the phase and quadrature components. The MTI filtering circuit extracts the high frequency components of the signal that are associated with the moving targets. The Autocorrelation & CFM parameters estimation circuit extracts the information concerning the speed, variance and power of the color signal.

The PW demodulation & CW Digitizing circuit demodulates the Doppler signal and digitizes the CW Doppler signal. The Doppler processing block receives the demodulated signal and extracts the FFT spectrum and audio component.

Processor board

The Processor board contains two CPU's.

1) The central processor in the CPU circuit
2) The ETX board

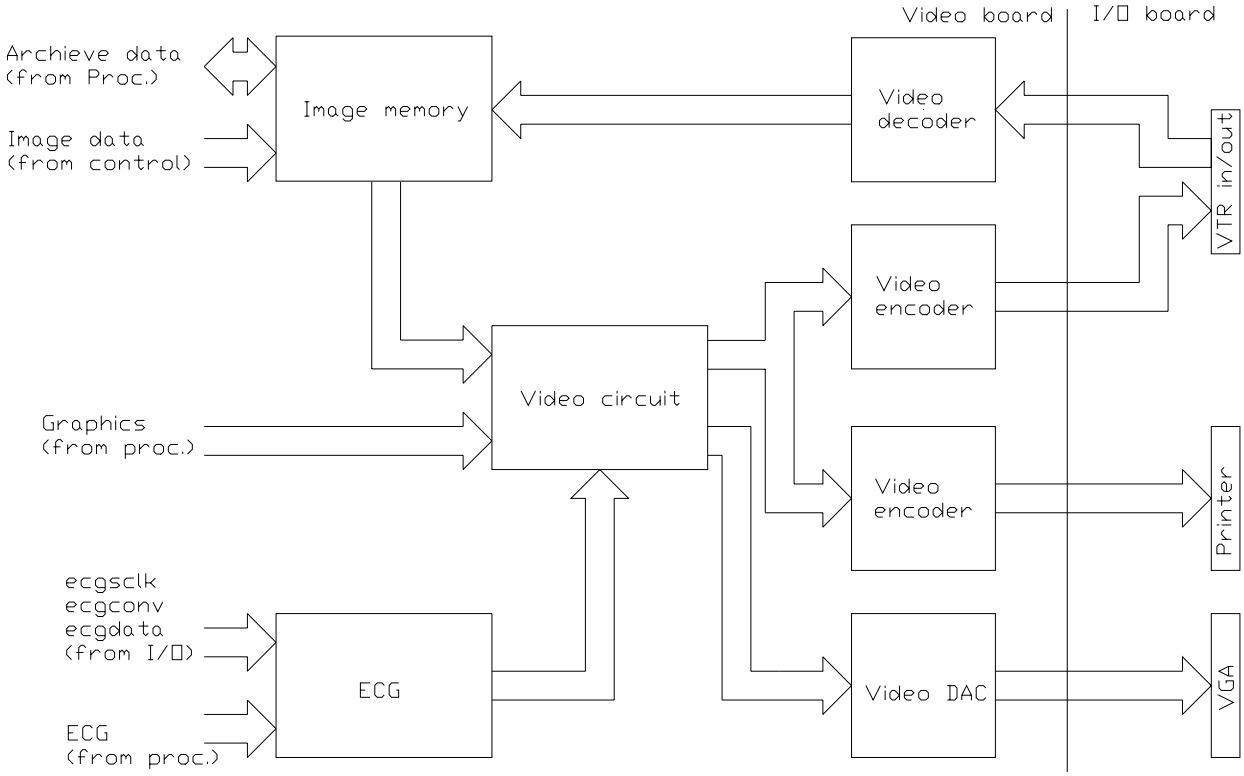


The central processor manages the system, and communicates with the keyboard, encoders and trackball.
The software located in this circuit contains the resident program and the AOD probe management tables.
The CPU circuit also controls the Graphic memory which makes it possible to superimpose the graphics on the ultrasound image.

The ETX board is a piggy back board that takes care of the digital archiving and connectivity like LAN and USB.
Archiving images is done by reading the Image memory and ECG memory on the video board.

Video board
The Video board contains three parts.

1) Video circuit
2) ECG
3) Image memory



The Video circuit generates the output signals for VGA and for the peripherals like printers and VCR.

The image data, ECG and graphics are converted to RGB and the encoders and DAC convert the signals in t the format of the involved peripheral.
The playback signal of the VCR is fed through the Video decoder into the image memory.

The ECG circuit processes the physiological signals for presentation on the board. The circuit filters the notch and extracts the ECG sync and sends the ECG signal to the processor board for synchronization with the signal being acquired.

The interpolated image data from the control board is stored in the image memory. When reviewing archived images, the data is coming from the processor board and stored in the image memory to be processed by the video circuit.

Graphics are mixed with either ultrasound data or archived data in the image memory as well.

5 Licenses

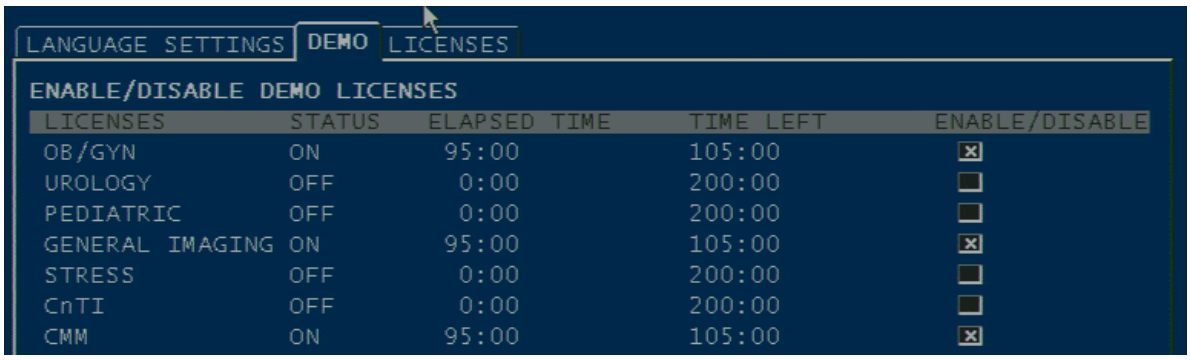
5.1 Installing new licenses

To install a new license, press MENU and select LICENSE.
The screen to enter the new licenses is displayed.
Enter the license code in the appropriate field and select OK.

5.2 Demo licenses

To enable and disable demo licenses it is required to start up the unit with the service key connected.

After start up press MENU and select SERVICE and then SETTINGS.
Now select the DEMO tab.



Check or un-check the enable/disable field to activate or deactivate the demo license.

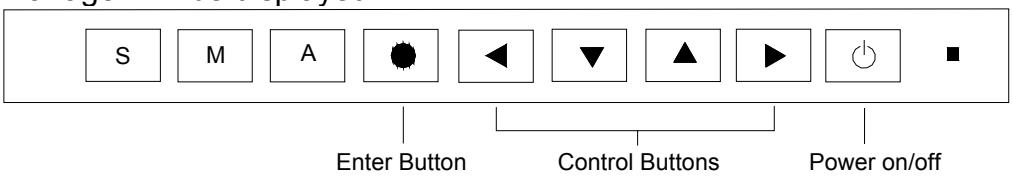
6 SERVICE INFORMATION

6.1 LCD screen settings

The 19” LCD Monitor, part # 91754 411302, is standard set to the following settings:

Brightness 50%
Contrast 100%
Color temp 8500K

To change the settings press the ENTER button on the LCD and the Screen Manager will be displayed.



Choose Brightness/Contrast/Color management by means of the control keys and press ENTER.
Change the settings and press ENTER to confirm.

6.2 Configuration screen

To display the configuration screen press the MENU key and select SYSTEM INFO.

By means of the EXPORT button it is possible to export configuration data to the USB pen drive. The data is exported in .txt format.

There are 4 or 5 tabs; each tab displays its specific information.

General

SERIAL NUMBER	SN xxxxx - ESAOTE2750001	
SYSTEM SOFTWARE	RES 1.01	ODS 7.01
	STD 7.02	013-142 [010]
VIDEO STANDARD	PAL	
MODULES:		
NONE		
LICENSES:		
CARDIAC		
VASCULAR		
GENERAL IMAGING		
TEI		

The general tab displays:

- The unit serial number
- System software version (STD). The first three or four digits (the digits 7.02 as shown above) refer to the software release installed in the processor (CPU). The other nine digits (digits 013-142 [010]) refer to the software release installed in the ETX board, where the Windows® operating system is managed.
- The video standard. PAL or NTSC.
- The installed licenses and Modules.

Boards

INPUT	[00]
CONTROL	[12]
DOPPLER	[00]
KEY	[00]
KEY TGC	[00]
PROCESSORS	[14]
POWSUPPLY	[02]
TRX1	[00]
TRX2	[00]
VIDEO	[01]

The board tab shows the installed boards with their configuration index. (C.I.).
The configuration index indicates the hardware level of the board.

Firmware

CONTROL	8602750850 N	[01.011A.J494]
CONTROL	8602750860 L	[02.011A.J208]
CONTROL	8602750870 J	[03.008A.J112]
CONTROL	8602750880 I	[04.008A.J004]
CONTROL	8602750890 B	[05.002A.J004]
CONTROL	8602750900 B	[06.002A.J003]
CONTROL	8602750910 B	[07.002A.J003]
CONTROL	8602750920 B	[08.002A.J003]
CONTROL	8602750930 B	[09.002A.J003]
CONTROL	8602750940 E	[10.005A.J004]
CONTROL	8602750950 C	[11.003A.J006]
CONTROL	8602750960 D	[12.004A.J008]
CONTROL	8602750970 D	[13.004A.L067]
CONTROL	8602750980 B	[14.002A.J005]
CONTROL	8602750990 B	[15.002A.J005]
CONTROL	8602751000 B	[16.002A.J005]
DOPPLER	8602750660 K	[01.009A.H007]
DOPPLER	8602750670 I	[02.008A.H356]
PROCESSORS	8602750520 B	[01.002A.B281]
PROCESSORS	8602750530 Q	[02.011A.B590]
PROCESSORS	8602750540 K	[03.010A.B059]
PROCESSORS	8602750500 H	[04.007A.L029]
PROCESSORS	8602750510 I	[05.008A.I002]
PROCESSORS	8602750570 H	[06.007A.L029]
PROCESSORS	8602750580 H	[07.007A.I010]
VIDEO	8602750240 F	[01.005A.I251]
VIDEO	8602750250 L	[02.009A.Q053]
POWSUPPLY	8602750010 D	[01.003A.K003]

The Firmware tab shows the firmware levels of the installed boards.
The FLASH EPROMS on the boards are partitioned in several sectors and each sector can be separately programmed.

Licenses

LICENSES	STATUS	ELAPSED TIME	TIME LEFT
OB/GYN	OFF	0:00	500:00
UROLOGY	OFF	0:00	500:00
STRESS	OFF	0:00	500:00
CnTI	OFF	0:00	500:00
DICOM	OFF	0:00	500:00
CLIP	OFF	0:00	500:00
CMM	OFF	0:00	500:00
TVM	OFF	0:00	500:00
VPAN	OFF	0:00	500:00
3D/4D	OFF	0:00	500:00
XSTRAIN	OFF	0:00	500:00

The Licenses tab shows the status of the demo licenses. With the aid of the service key it is possible to activate or de-activate demo licenses.
The listed licenses can be activated by entering the license code, see chapter 5.1 Installing new licenses on page 31. When activated the involved license will be displayed in the general tab.
See chapter 5.2 Demo licenses, page 31 for more information on how to activate or de-activate the demo license.

6.3 Unit self test

At power-on, the processor board executes a self test to check the following:

- The configuration index and firmware level of the installed boards.
- The installed software version.

The result is displayed in the configuration screen which is displayed during start up or by pressing MENU and SYSTEM INFO.

While performing the self test the unit checks whether new features (e.g. licenses) are installed.

6.4 Unit conflicts

In case of conflicts (at start up) between hard- and software levels in the unit, the system stops while displaying the configuration screen.
A warning message is displayed such as:

System configuration error: board(s) not available or not compatible.

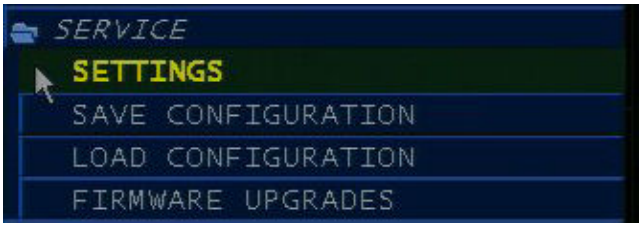
The fields causing the conflicts are displayed in red in the BOARDS tab in the configuration screen.
Press CANCEL to proceed to the next screen.

6.5 Service menu

The service menu will only be active when the unit has started up with the service key connected.

The key provides access to the Service menu. The key can be pressed both in real-time and in freeze state. The system displays this window:

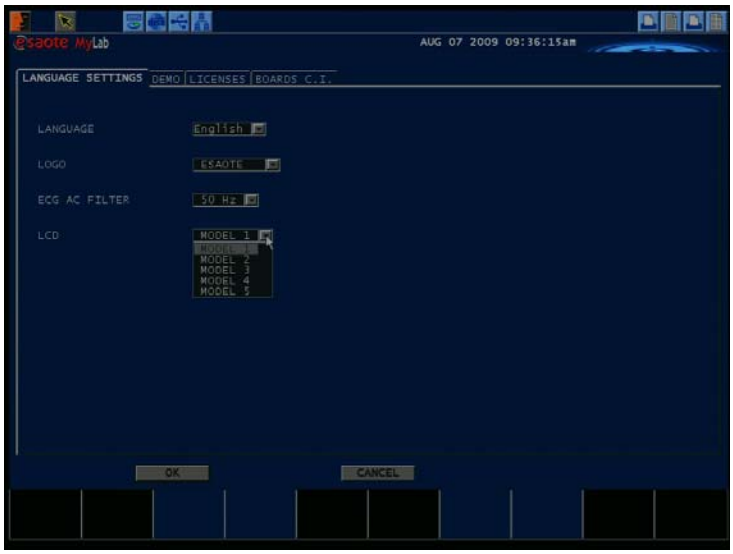
Select the SERVICE option with the trackball and press **ENTER** to continue. The system displays the following Service menu:



Settings

The settings menu makes it possible:

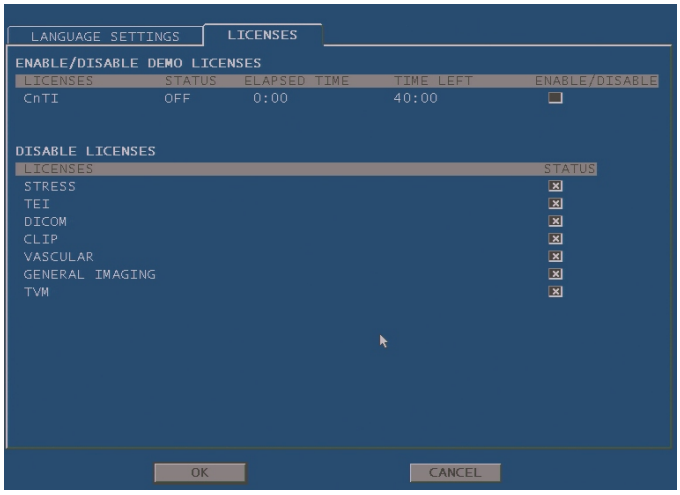
- To choose the default language
- To set the ECG notch filter
- To set the LCD Display
- To activate/deactivate (demo) licenses



Setting Parameters:

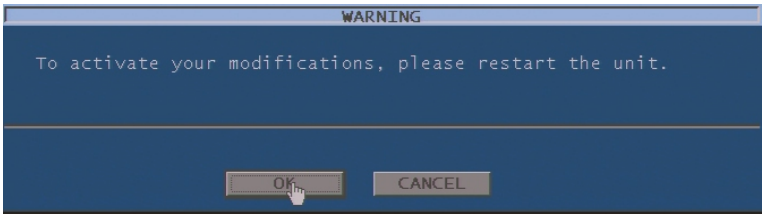
- Position the trackball on the field to be changed and press ENTER to confirm.
- Use the alphanumeric keyboard to type in the characters.
- In the drop down menus, select the required option and press ENTER to confirm.
- Press OK to confirm.

The demo licenses can be activated or de-activated in the Licenses tab.
The active licenses and the remaining time of the demo licenses are displayed.



Click OK to confirm the changes.

The following screen is displayed:



Click OK to confirm.

Save/Load configuration
This procedure allows to save and retrieve all the factory settings (both user and service presets), the unit Serial Number and the unit licenses (demo licenses are not saved!) in the internal E2PROM.
It is recommend to save the system configuration when the settings are changes or the unit is updated.

6.6 Soft- and firmware update

Usually the procedure to upgrade MyLab40/MyLab20Plus with a new software release has three steps:
- Firmware upgrade
- Windows upgrade
- Internal processor re-synchronization

Typically the support used to upgrade the unit is a DVD containing all necessary files. Some software releases could have specific upgrading procedures (e.g. if the BIOS upgrade should be run). Refer to the protected service website to know if a software release requires specific instructions.

NOTE
Before proceeding with the upgrading procedure save both the user presets and the configuration.

The upgrading procedure will remove the drivers of all PC printers added by the service. The PC printer driver CDs are necessary to install again the printers.

The upgrading procedure will cancel the network settings. Before starting the upgrade, copy all the settings so that the network can be configured again.

The upgrading could remove the Dicom settings. Before proceeding with the upgrade, copy the Dicom configuration (both server and printer) so that Dicom can be configured again should it be necessary.

Firmware Upgrade

The firmware upgrade is performed through the Service menu.

1. Turn on the unit with the Service key inserted.
2. Enter Real-Time.
3. Press ARCHIVE REV and verify if there are archived exams. If so, open the first and last exams and annotate which images are archived and if the report exists (the same check will be asked at the end of the upgrading).
4. Access to the Service menu.
5. Select the option “Firmware upgrades” using the trackball and the ENTER key to confirm.
6. The system displays the window (right) allowing the selection of the upgrade source drive. Choose the drive and press OK to confirm.
7. The system shows a list of the files to be installed. All the files marked with a cross will be loaded. Press OK to start the programming procedure
8. The upgrade procedure is automatically executed: once reprogramming has been started, a series of screens indicating the progress of the upgrade procedure appears on the display.
9. At the end of the upgrade procedure, the system displays the Start Exam window.

NOTE
If the upgrade procedure has not been carried out correctly, an error message will be displayed to indicate which file has not been reprogrammed correctly. In this case, the procedure must be repeated.

Windows Upgrade

10. Leaving the upgrading CD inserted, switch the unit off, remove the service key and then switch the unit on again.

NOTE
The service key must be removed in order to be sure that the upgrading procedure ends successfully.

11. At start up the HD programming from CD is automatically started. The upgrade progress can be viewed by pressing the keys Ctrl + Alt + ARCHIVE REV from Real-Time: the upgrade status bar is displayed on unit screen.
12. The CD will be ejected automatically when finished.

Processors Re-synchronization

13. Switch off and on again
14. Wait for the Start End window. During this step (that could last some minutes) the HD icon stays grey since the system is re-programming its devices.
15. Press the MENU key.
16. Select “General preset” option.
17. Once you have accessed to the preset menu, press OK to confirm.
18. Wait till the hourglass disappears and then switch the system off by pressing the **STARTEND** key (shut down key) for 3 seconds.
19. Turn the unit on and enter Real-Time.
20. Press **FREEZE** and then **POINTER**. Verify that there is no purple shadow around the displayed mouse cursor. If so, insert the upgrading CD and repeat the procedure starting from point 10.
21. Press ARCHIVE REV and verify the correspondence of the first and last exams. Should any inconsistency be noted, run the “Recover archive” procedure (Hard Disk menu).

At the end of the upgrading procedure, insert again the service key to configure, if necessary, the PC printer, the network and the Dicom server. Remind to save the new configuration (“Save & Load Configuration” option of the Service menu) and to print out the new SYSTEM INFO screen.

NOTE
If the upgrading procedure is interrupted before its completion, remember to start it again from the beginning.

6.7 Backup and retrieve a local archive.

It is strongly recommended to make, on regular base, a backup of the patient data at the end-users site. This will minimize data lost. Additional, an extensive local archive could slow the unit operation down.

Backup
In ARCHIVE REV select the exams to backup.

To select more exams, just hold the shift key (alpha numeric keyboard) and select the exams.

- Select COPY (lower left corner, software key) and select the destination for the backup.

Retrieve
In ARCHIVE REV select the source (cd/dvd, usb etc.) from were the archive should be retrieved (upper right corner, software keys). In the following picture a USB drive will contain the archive.

- Select the exams that have to be retrieved.
- Select COPY.
- Select LOCAL ARCHIVE.

Now the selected exams are copied from the selected source (in this case a USB drive) to the local archive.

6.8 Hard disk replacement

Whenever the programmed Hard Disk has to be replaced, please carefully follow the detailed procedure below.

NOTE
The programmed Hard Disk is always delivered by Esaote with the last software release installed. Please remind to install the last software release in the unit if not already done.

Procedure
Once the Hard Disk has been replaced and the Processor board has been reinstalled, set the following parameters:

- Press MENU key and select GENERAL PRESET.
- Set the Data/Time.
- Press OK to confirm.
- Wait till the message appears, press OK and then turn the unit off by pressing the Shut Down key.
- Turn the unit on.
- If necessary, re-configure the network (Hard Disk Configuration menu).
- If necessary, set the DICOM Server and Printer configuration.
- See Section 6.15 for PC printer installation procedure
- If necessary, install the PC printer and set the printing preferences of the PC printer (PC Printer Configuration menu).

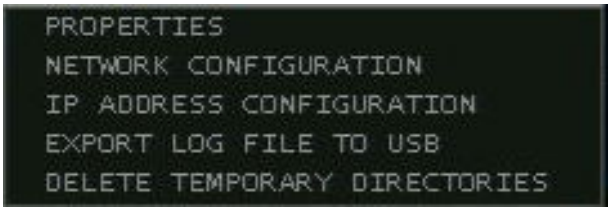
If the presets (such as User Presets, Probe Presets, Application Measurements presets) have been previously saved through the option “Save & Load Presets” of the MENU key, they can be loaded to be restored only when the “Save & Load Preset” operations are done with the same software release.

6.9 Hard disk menu

To activate the HD Configuration menu the trackball has to be switched to pointer mode: press **FREEZE** and then the key to activate it.

6.9.1 Hard Disk menu in exam mode

Hard Disk icon
Place the pointer on the Hard Disk icon and press **UNDO** key. The system displays the following Hard Disk configuration menu:



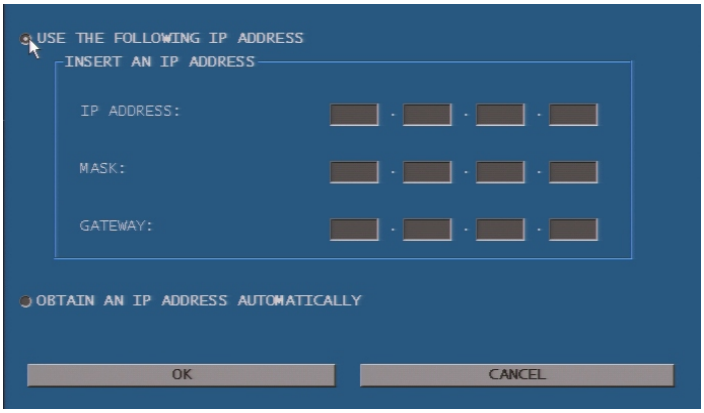
Place the pointer on the desired option and press **ENTER** to confirm the selection.

Properties
See the Operator manuals for more details
The system displays the free disk space, the name and the IP address of the unit and its AE Title. This option is always available (i.e. it does not require the Service key to be shown).

Network Configuration
The Network Configuration can be modified only if the Service key is inserted before switching on the unit.

This option allows the network to be configured. It is necessary to have a working knowledge of networking environments. Prior to starting the configuration procedure, determine characteristics of the network like the addressing mode (fixed or DHCP), the default gateway IP address, if a DNS server is present and so on. Thus it is suggested to contact the network administrator before proceeding with the configuration. The Network board inside the MyLab40/MyLab20Plus works at 100 Mbit per second.
For a detailed description how to set up a network, see section 6.10.

IP Address Configuration
This option allows the user to set the network or to modify some parameters (i.e. it does not require the Service key to modify the IP Address Configuration). In this window the user can define a dynamic or static addressing. In this latter case the user can set or modify the IP address, the subnet mask and the gateway address. If more network parameters have to be modified go to the “Network Configuration” option as described in the previous section (service key is needed).



Export log files to USB
This option allows the user to save onto a USB key the log files. To save the log files, insert a USB dongle into one of the two connectors on the rear panel and activate the procedure.

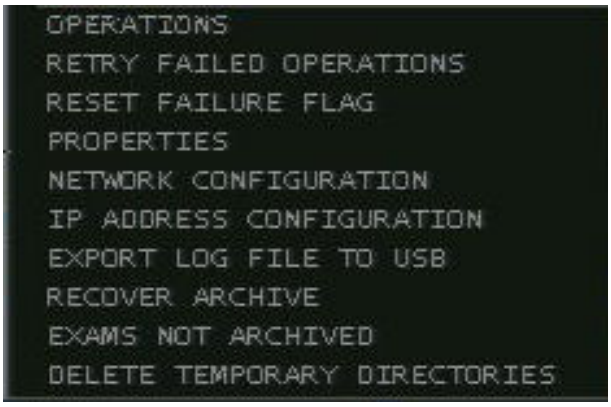
Whenever a problem occurs in the field it is strongly recommended to provide Esaote Service with the unit log file.

Delete temporary directories.
This operation will delete the temporary directories. Please check that no operation is in progress, otherwise this data will be lost.

6.9.2 Hard Disk Menu in Archive Review

When in Archive Review the Hard Disk configuration menu is different:

Hard Disk icon
Place the pointer on the Hard Disk icon and press **UNDO** key. The system displays the following Hard Disk configuration menu:



Place the pointer on the desired option and press **ENTER** to confirm the selection.

Operations
Here all operations on the hard disk will be displayed (e.g. exporting, deleting etc.). Operations can be aborted, retried, deleted or details concerning the operation can be displayed.

Retry failed operations
If an operation fails the hard disk icon will change.

This operation will retry the last failed operation.

Reset failure flag
This operation will reset the HD icon from

to

Recover Archive
The system has been designed to preserve as much data integrity as possible. This procedure allows rebuilding of the archive, if the hard disk is corrupted.

WARNING
Do not switch the unit off while this procedure is running. The Hard Disk could be damaged.

Exams Not Archived
See the Operator manuals for more details
This option shows the list of exams, which have been performed and not archived into the local database. From this window you can select the exams to be saved onto the local hard disk.

6.10 Network Configuration

In order to connect a unit to a network (LAN or wireless LAN), several settings must be set accordingly. These settings involve windows settings as well as settings in the resident program. Hereinafter follows a description of which settings should be set for both LAN and wireless LAN. For LAN settings only the **Network Configuration section** 6.10.2 is relevant. These procedures require a service key.

NOTE
It is necessary to have a working knowledge of networking environments. Prior to starting the configuration procedure, determine characteristics of the network like the addressing mode (fixed or DHCP), the default gateway IP address, if a DNS server is present and so on. Thus it is suggested to contact the network administrator before proceeding with the configuration.

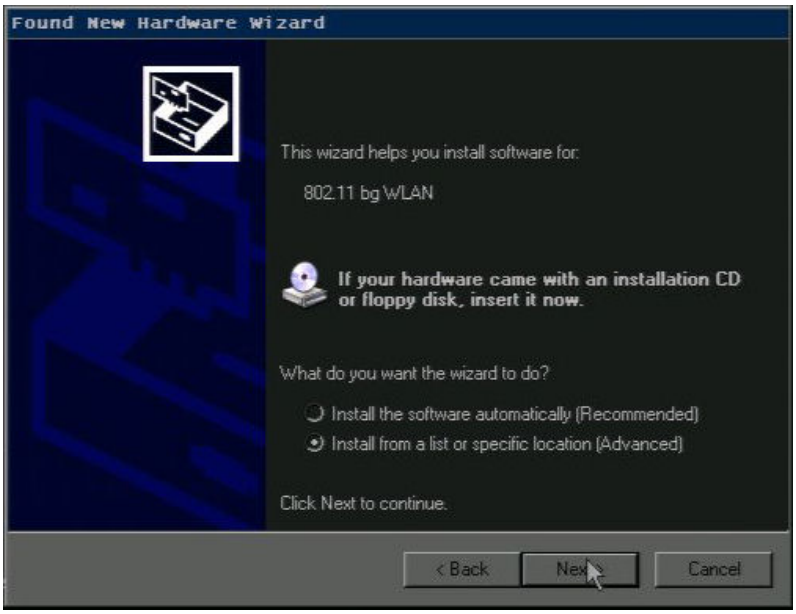
6.10.1 WiFi USB adapter installation

The installation of the WiFi USB adapter has to be done under Windows so the service key should be inserted before switching on he unit.

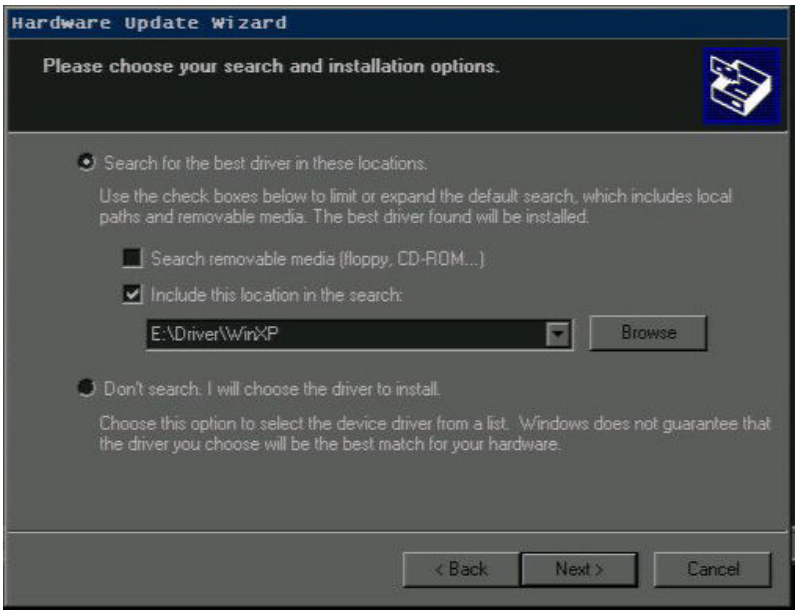
- After starting up the unit go to “ARCHIVE REV”.
- In “ARCHIVE REV” press ALT + ESC on the alphanumeric keyboard to switch to windows.
- Once in windows insert the WiFi USB adapter in the unit. The following window will pop up.

Found New Hardware Wizard
Welcome to the Found New Hardware Wizard
Windows will search for current and updated software by looking on your computer, on the hardware installation CD, or on the Windows Update Web site (with your permission).
Can Windows connect to Windows Update to search for software?
Yes, this time only
Yes, now and every time I connect a device
No, not this time
Click Next to continue.
< Back
Next >
Cancel

- Select “No not this time” then select next. The following window will pop up.


Found New Hardware Wizard
This wizard helps you install software for:
802.11 bg WLAN
If your hardware came with an installation CD or floppy disk, insert it now.
What do you want the wizard to do?
Install the software automatically (Recommended)
Install from a list or specific location (Advanced)
Click Next to continue.
< Back
Next >
Cancel

- Select “install from a list or specific location” then select next. The following window will pop up.

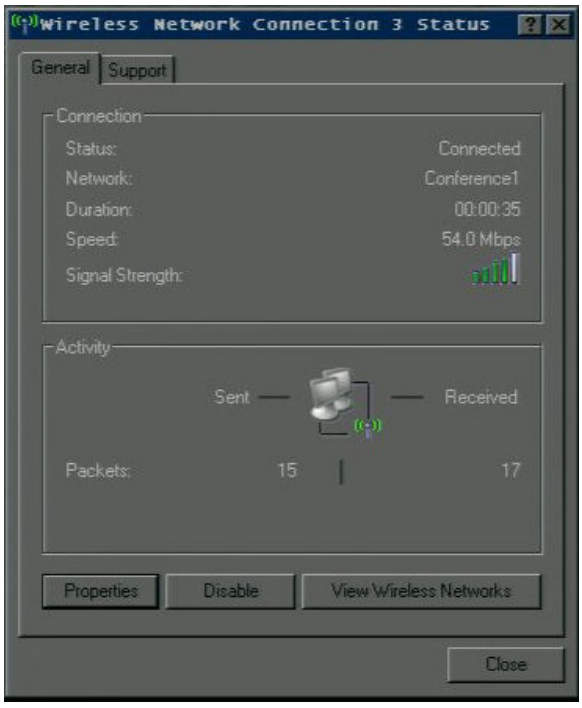

Hardware Update Wizard
Please choose your search and installation options.
Search for the best driver in these locations.
Use the check boxes below to limit or expand the default search, which includes local paths and removable media. The best driver found will be installed.
Search removable media (floppy, CD-ROM...)
Include this location in the search:
E:\Driver\WinXP
Browse
Don't search. I will choose the driver to install.
Choose this option to select the device driver from a list. Windows does not guarantee that the driver you choose will be the best match for your hardware.
< Back
Next >
Cancel

- Select “include this location in the search” and select the drive and the path for the drivers of the WiFi USB adapter (CD must be inserted). Then select next. The following window will pop up.

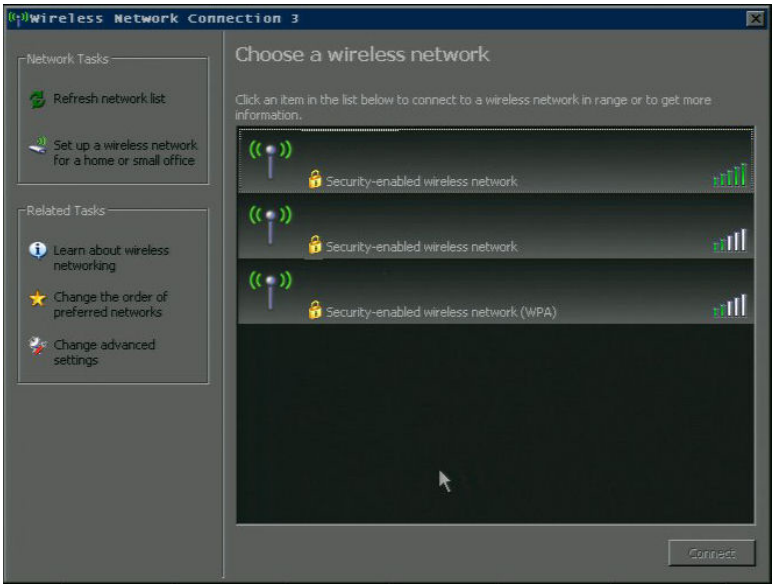
Found New Hardware Wizard
Completing the Found New Hardware Wizard
The wizard has finished installing the software for:
ASUS USB Wireless Network Adapter
Click Finish to close the wizard.
< Back
Finish
Cancel

- Select finish to finalize the installation.
- Return to windows (CTRL + ESC in ARCHIVE REV)

- In the right corner of the taskbar double-click on the “wireless network connection icon”. The following window will pop up.

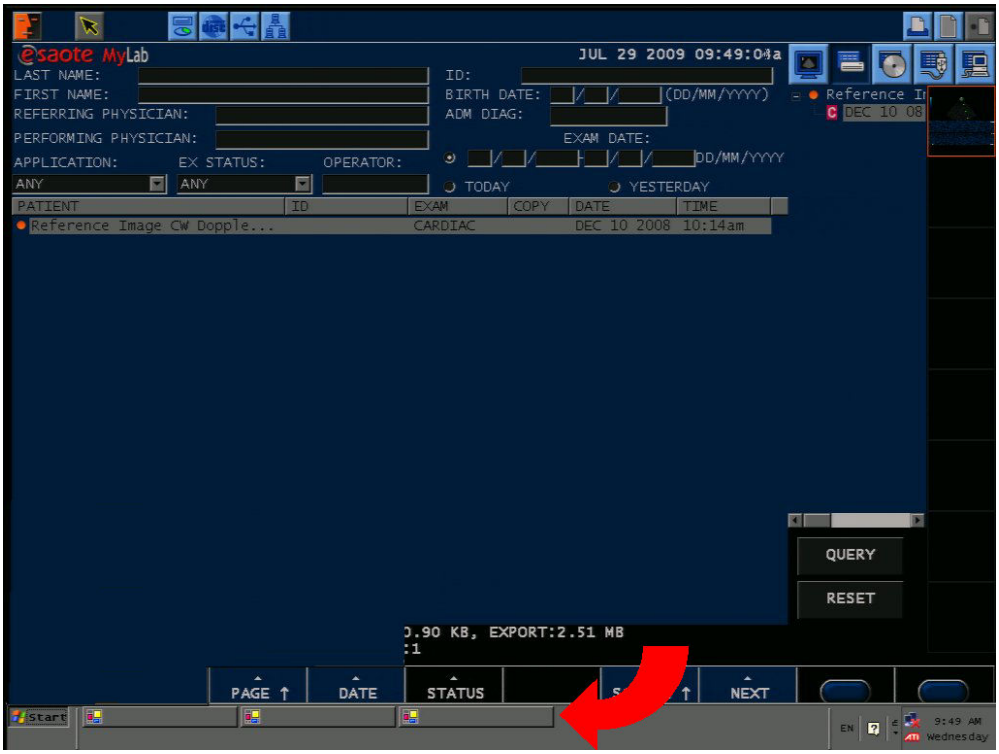


- Select “View Wireless Networks”. The following window will pop up.


Wireless Network Connection 3
Network Tasks
Refresh network list
Set up a wireless network for a home or small office
Related Tasks
Learn about wireless networking
Change the order of preferred networks
Change advanced settings
Choose a wireless network
Click an item in the list below to connect to a wireless network in range or to get more information.
Security-enabled wireless network
Security-enabled wireless network
Security-enabled wireless network (WPA)
Connect

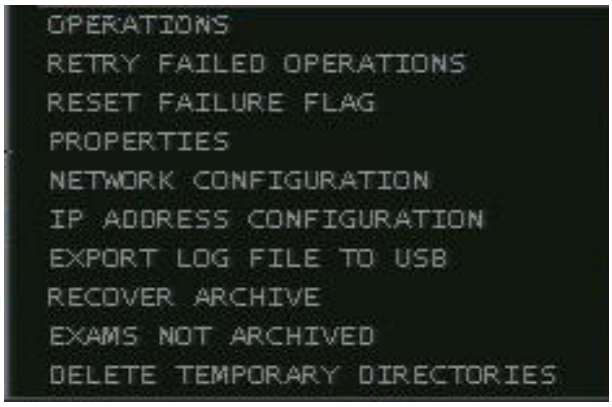
- Select the wireless network of your choosing. It could be that a network key is needed to be able to login on the network, if this is the case contact the network administrator.

- When the connection is established close the “wireless network connection menu” and return to the resident software of the unit. To return to the resident software of the unit click on the most right tab on the taskbar (see following picture).



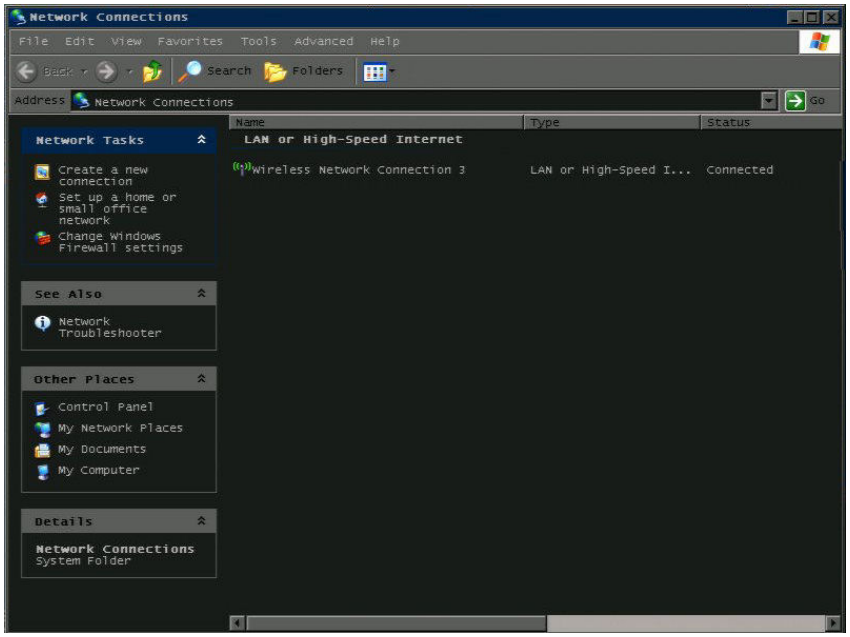
6.10.2 Network Configuration (LAN & WLAN)

- In ARCHIVE REV Place the pointer on the Hard Disk icon and press UNDO key. The system displays the following Hard Disk configuration menu:

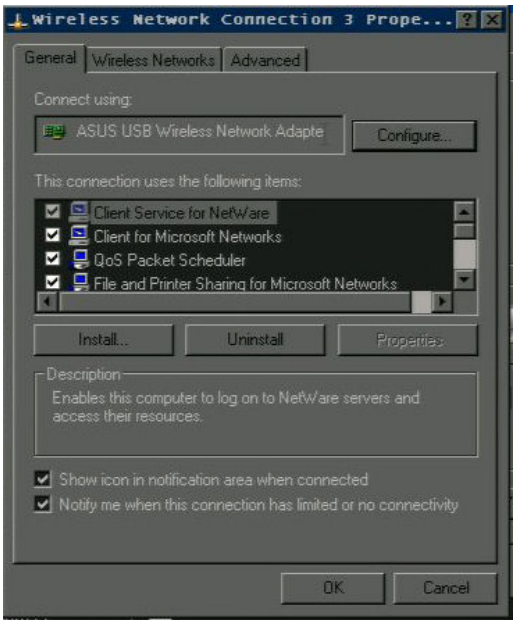


The Network Configuration can be modified only if the Service key is inserted before switching on the unit.
Some parameters such as: IP address, subnetmask and gateway can also be configured with the “IP address configuration option” (see next section). For the “IP address configuration option” the service key is not needed.

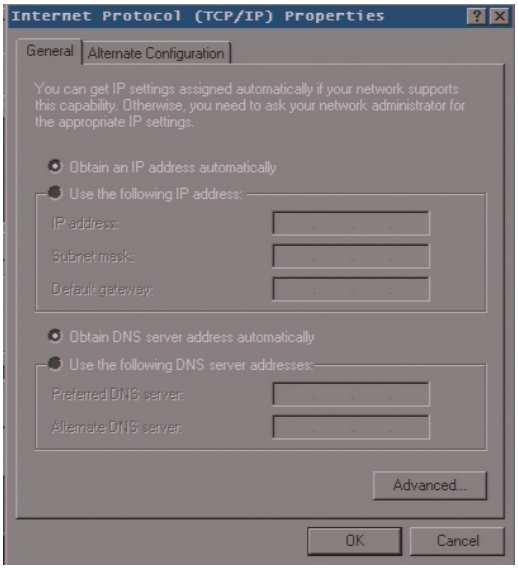
- Place the pointer on the “network configuration option” and press ENTER to confirm the selection. Once activated, the equipment displays the Windows XP Network configuration menu.



- Double click on the “Wireless Network Connection icon” in case of WLAN or on the “Local Network Connection icon” in case of LAN, and select properties. The system displays the following screen:



- Place the cursor on the “Internet Protocol (TCP/IP) option” and highlight it by pressing **ENTER**.
- Place the cursor on “Properties” button and activate it by pressing **ENTER**. The system displays the following TCP/IP configuration menu:


Internet Protocol (TCP/IP) Properties
General
Alternate Configuration
You can get IP settings assigned automatically if your network supports this capability. Otherwise, you need to ask your network administrator for the appropriate IP settings.
Obtain an IP address automatically
Use the following IP address:
IP address:
Subnet mask:
Default gateway:
Obtain DNS server address automatically
Use the following DNS server addresses:
Preferred DNS server:
Alternate DNS server:
Advanced...
OK
Cancel

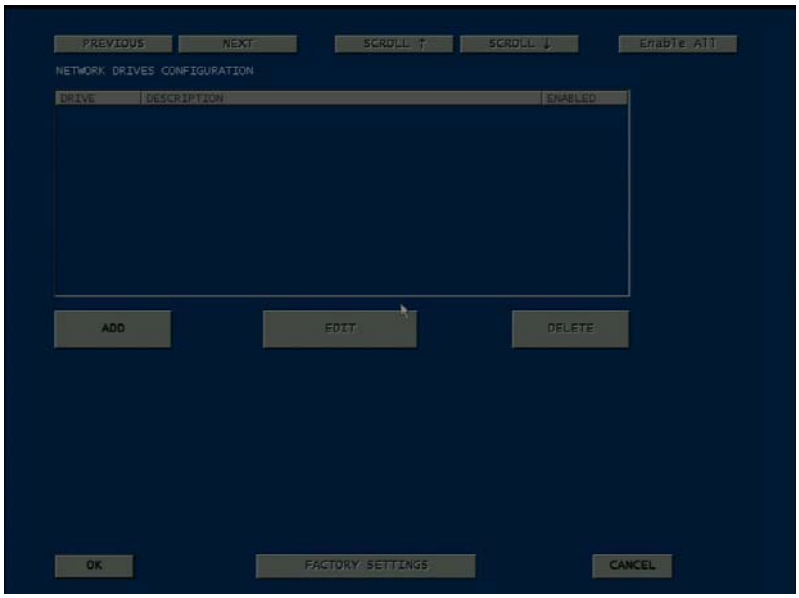
This menu allows selecting either a fixed IP address or a DHCP (Dynamic Host Configuration Protocol) address and to set the DNS addresses, when necessary.

- Set the desired parameters and press OK to confirm. The network settings will be operative at next start up.

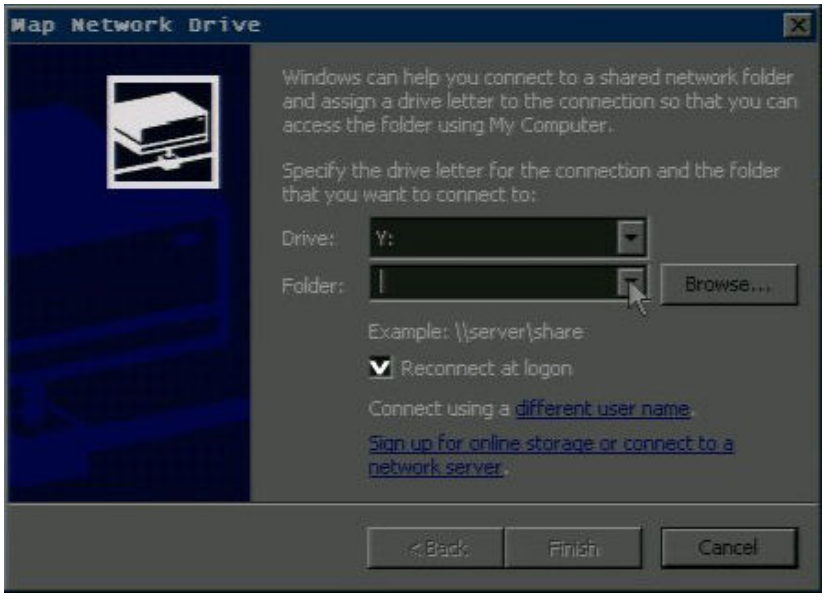
6.11 Setting up a network directory.

Assumed that the Network Configuration is set as described in paragraph 6.10, this is the procedure to set up a network drive, which can be used for archiving purposes. It is suggested to contact the network administrator before proceeding with the configuration.

- Press MENU key.
- Select the “Network Directory” option.
- The system displays the following menu.

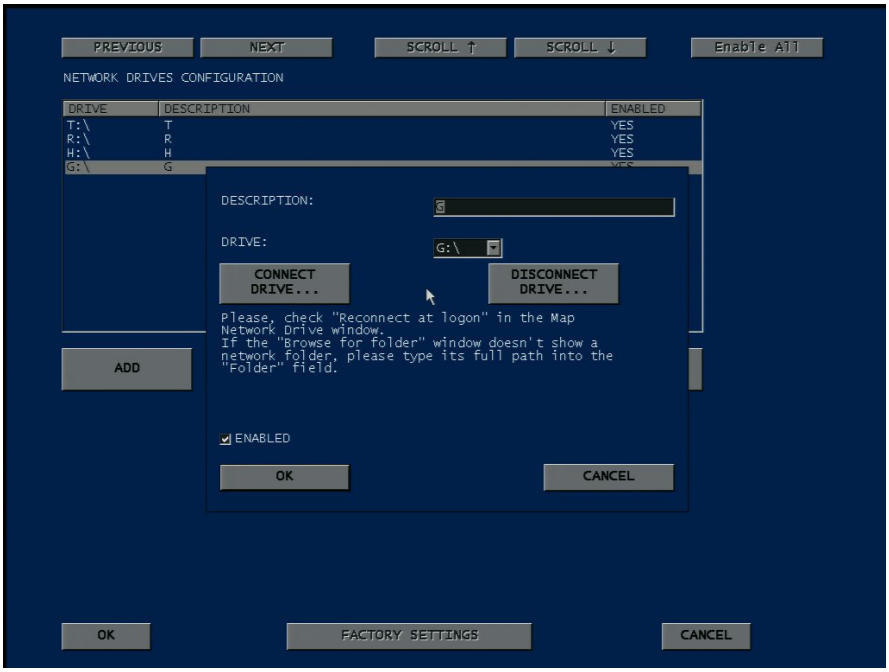


- Select ADD.
- Select connect drive. The system displays the following menu.


Map Network Drive
Windows can help you connect to a shared network folder and assign a drive letter to the connection so that you can access the folder using My Computer.
Specify the drive letter for the connection and the folder that you want to connect to:
Drive:
Y:
Folder:
Browse...
Example: \\server\share
Reconnect at logon
Connect using a different user name.
Sign up for online storage or connect to a network server.
< Back
Finish
Cancel

Select a drive letter and specify the shared folder on the network, which you want to use as network directory (this is called mapping a network drive).

- Mark “Reconnect at logon”.
- Select finish to return to the “add screen”. If windows asks for a username and a password, enter these and let windows remember them.

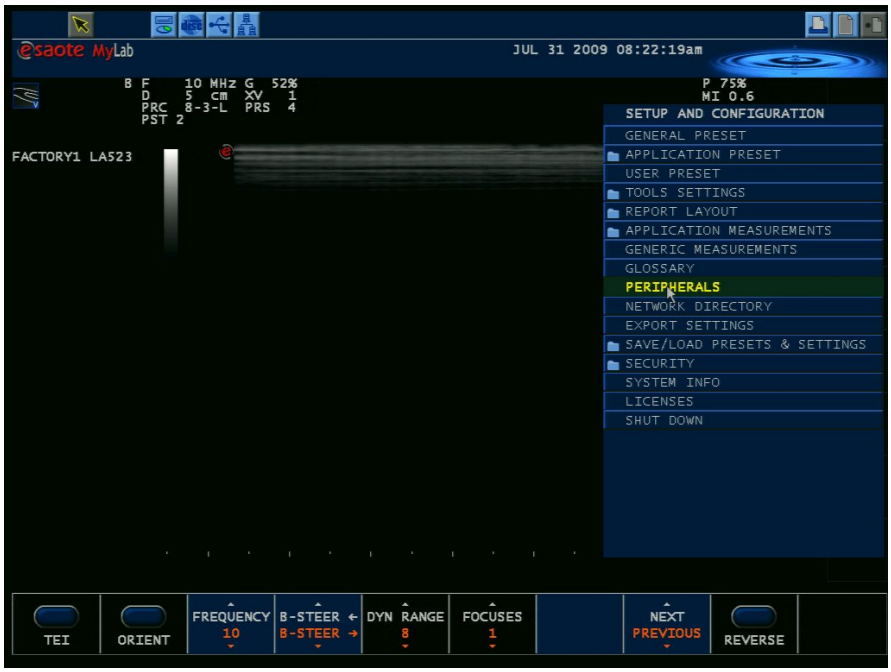


- Enter a description and the drive letter, which has just been mapped.
- Select ok.
- Also select ok in the network drives configuration menu.
- To activate the modifications, please start a new exam, press.

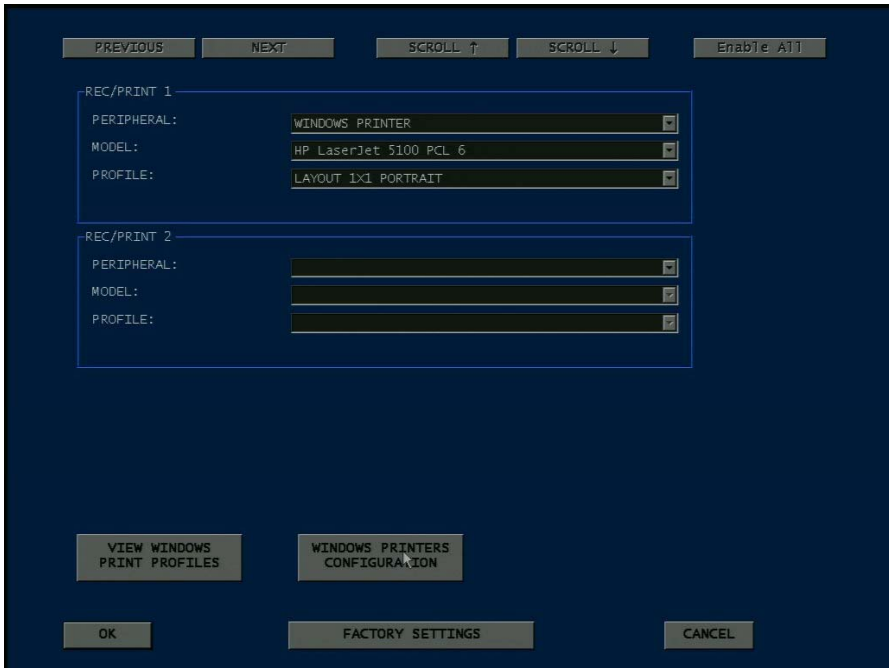
- Now in archive rev you will be able to export your data to your network directory.

NOTE
Whenever changes have been made to existing network drives, these will not work anymore after rebooting the system (error will be displayed). All network drives have to be removed and reinstalled. The following procedure must be followed.

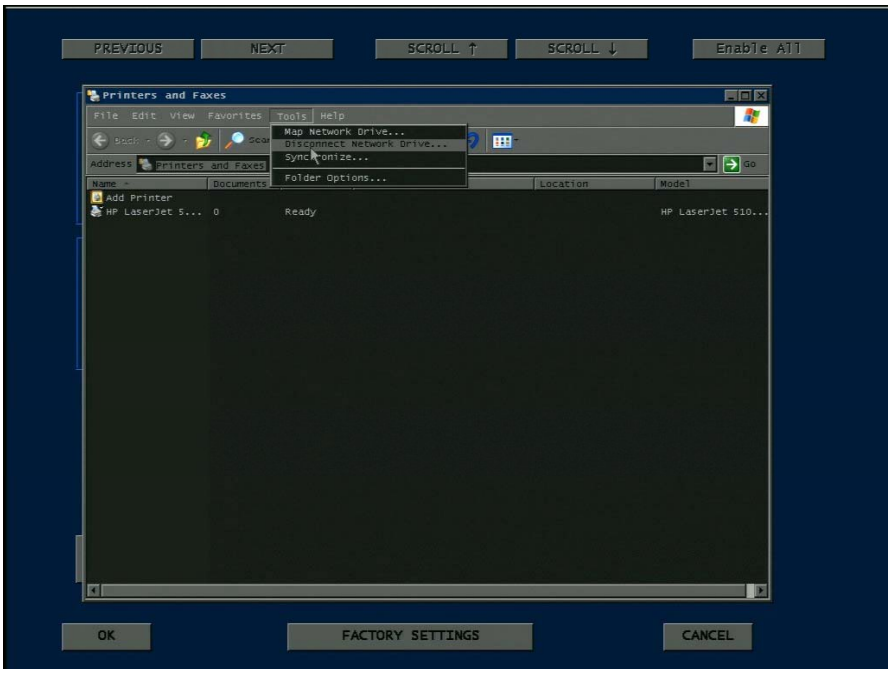
- In real time press the MENU key.



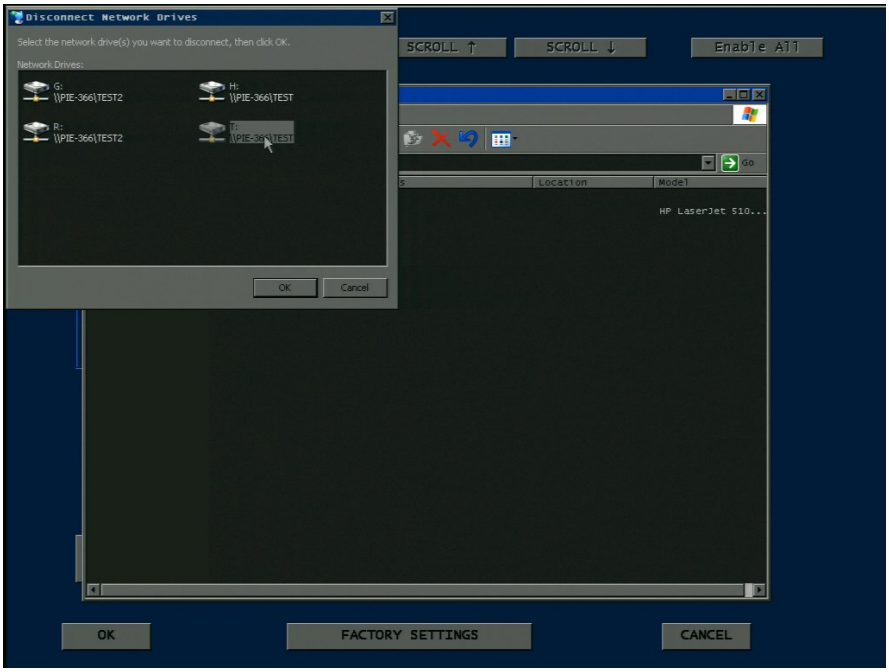
- Select “Peripherals”. The following screen will be displayed.



- Select “Windows printers configuration”. The following screen will be displayed.



- In the “Tools tab” select “Disconnect network drive”. The following screen will be displayed.



- Disconnect all drives.
- Close all windows screens. And return to “Add peripherals screen”
- Select ok to return to the real time mode.
- Press the MENU button again and select the “Network Directory” option.
- Also here delete all network drives.
- Select ok twice to return to the real time mode.
- In order for the changes to take effect a new exam has to be started, Press START END

- After starting a new exam, the network directories can be remapped as described above.

6.12 Report and measure configuration

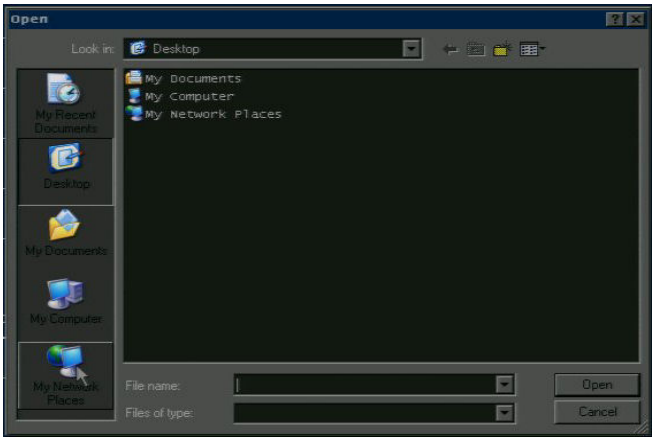
This procedure can be activated only if the Service key is inserted before switching on the unit.

Service personnel can customize the report, adding the centre logo, and can modify measurement descriptions.

Report Configuration
Procedure

- Press MENU key.
- Select the “Report Layout” option.
- Select “Header”.
- Select the desired application.
- The system displays the following menu

- Place the cursor on the field “Change” and press **ENTER**.
- The system opens the browser shown in the figure.



- Select the drive from which the logo has to be loaded and confirm.

NOTE
The logo should be PNG, BMP or JPG format.

Measure Configuration
The measurements descriptions, abbreviations and labels of both Cardiac and Vascular applications can be modified by the Service personnel.

Procedure
- Press MENU key.
- Select “Application Measurement” option.
- Select the desired application.
- The system displays the application measurement menu. To modify the description, place the cursor on the desired field and press **ENTER**.
- With the alphanumeric keyboard enter the new description.

CAUTION
It is possible to change only the descriptions but NOT the calculation combined to the measure. Each measure is associated to a specific preset calculation (a velocity measure can be freely named but it will always measure a velocity).

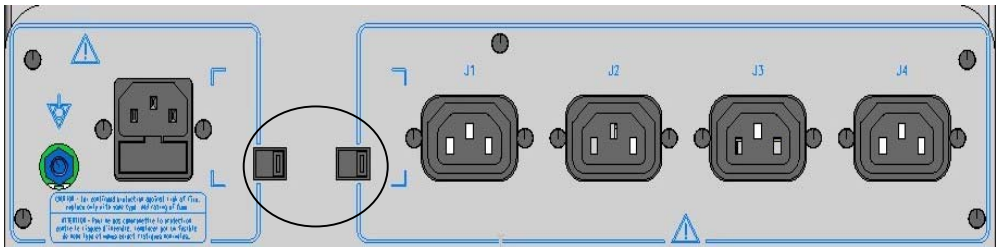
6.13 Changing mains voltage

The mains input voltage can be selected by means of the 2 main input voltage selectors, located on the socket panel.

NOTE
Both selectors should be placed in the same settings (either 120 or 240).
Disconnect the mains cable before changing the selectors.
Do not replace the system fuses with other types from the ones, specified by the manufacturer.

Replace the fuses accordingly after changing the input settings.
200 - 240 V => 250 V / T 5 A
100 - 120 V => 250 V / T 10 A

The fuses are located in the mains socket input.



6.14 Replacing the Processor Board Battery cell

The processor board contains a Lithium battery. It is strongly recommended to replace the battery cell every three (3) years. If the Processor board has to be stored, it will be necessary to first remove the battery.

WARNING
Replace only with the same or equivalent type. The Esaote supplier is: GP, Model CR2032, 3V 210mA/h.

WARNING

Avoid contact with a leaking battery as the contents are harmful.

Irritation, including caustic burns and injury may occur following exposure to a leaking battery.

Do not expose the battery to high temperature. Dispose batteries according to local regulation

Procedure

- For unit disassembly and gaining acces to the processor board see chapter 3.2 on page 11
- Replace the battery cell paying attention to cell orientation. The cell positive side of the cell (indicated with +) must be placed upwards.

WARNING
Incorrect replacement of the battery can cause battery explosion.

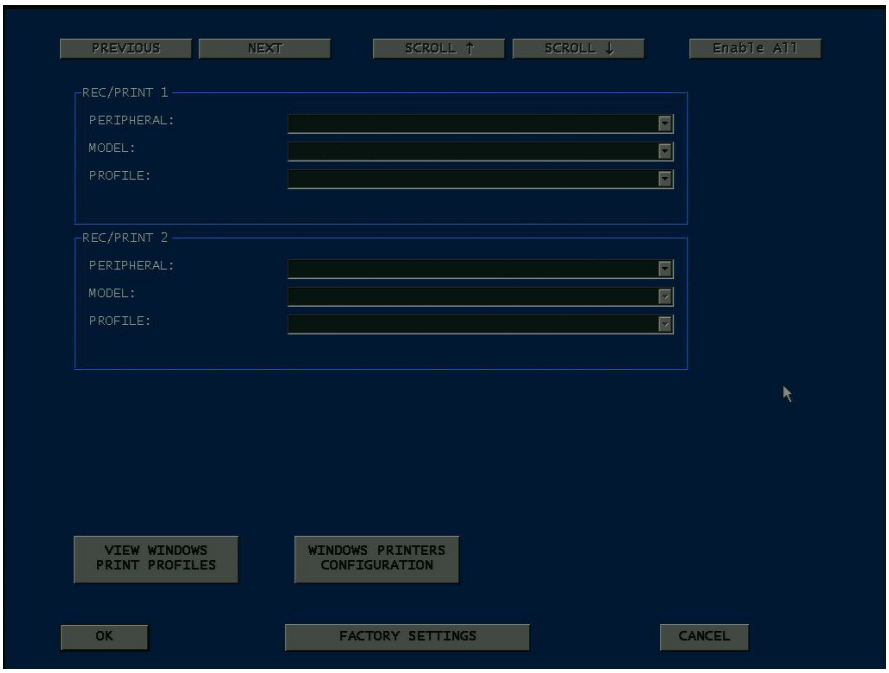
- Install the Processor board and Input boards again and close the unit.
- Connect an external USB keyboard and switch the unit on.
- Press Delete on the external keyboard and Press Alt + Ctrl + Archive Rev to enter the **System BIOS setup**
- The unit asks for a password, press enter on the USB extern Keyboard.
- In the System BIOS setup go to Basic CMOS Configuration and check the Date and Time.
- In the System BIOS setup go to Advanced CMOS Configuration and check if the option “Power Failure resume time ” is Always OFF.
- In the System BIOS setup go to Chipset Configuration and check if the option “Maximum CPU Frequency” is 1200 MHz.
- In the System BIOS setup write to CMOS and Exit.
- Disconnect the external USB keyboard.
- The system will enter Real Time mode.
- In Real Time mode press the **MENU** key.
- Select GENERAL PRESET.
- Set the data and time and press OK to confirm.

6.15 Printer driver installation

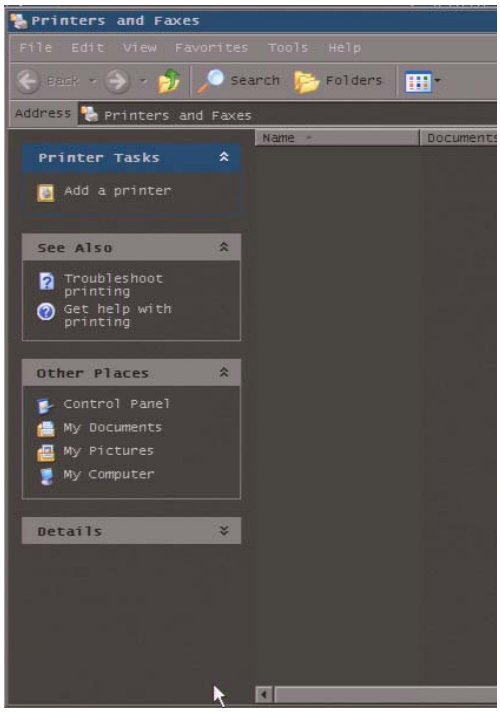
It is possible to install a Windows USB printer to print out reports and images.

NOTE
Before starting the installation procedure be sure to have the printer driver CD ready.

- Press the MENU key.
- Select the “peripherals” option.
- The system displays the following menu.



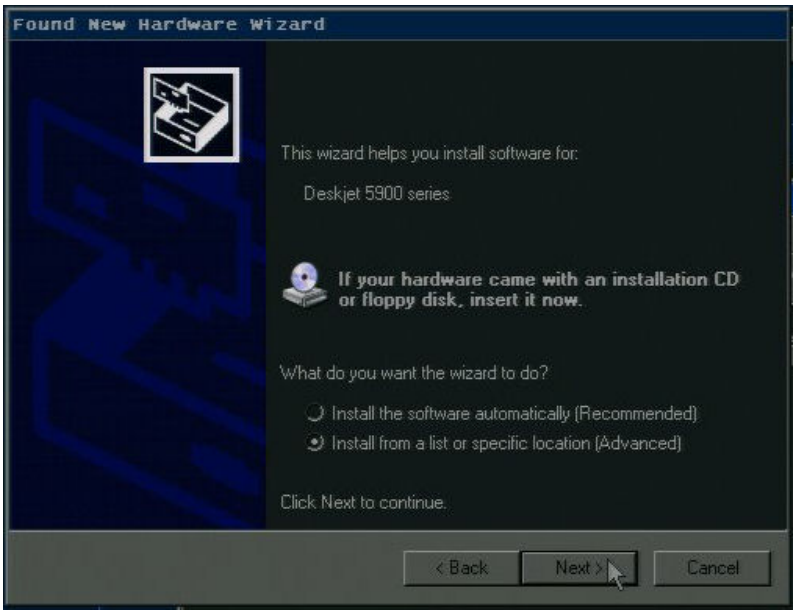
- Select the “windows printers configuration” option.



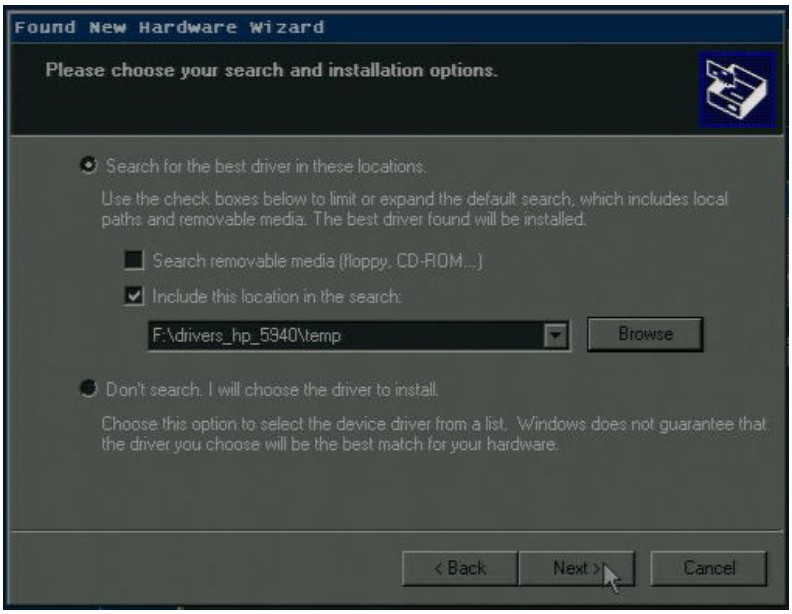
- Connect the USB printer with the MyLab unit. The following screen will pop up.

Found New Hardware Wizard
Welcome to the Found New Hardware Wizard
Windows will search for current and updated software by looking on your computer, on the hardware installation CD, or on the Windows Update Web site (with your permission).
Can Windows connect to Windows Update to search for software?
Yes, this time only
Yes, now and every time I connect a device
No, not this time
Click Next to continue.
< Back
Next >
Cancel

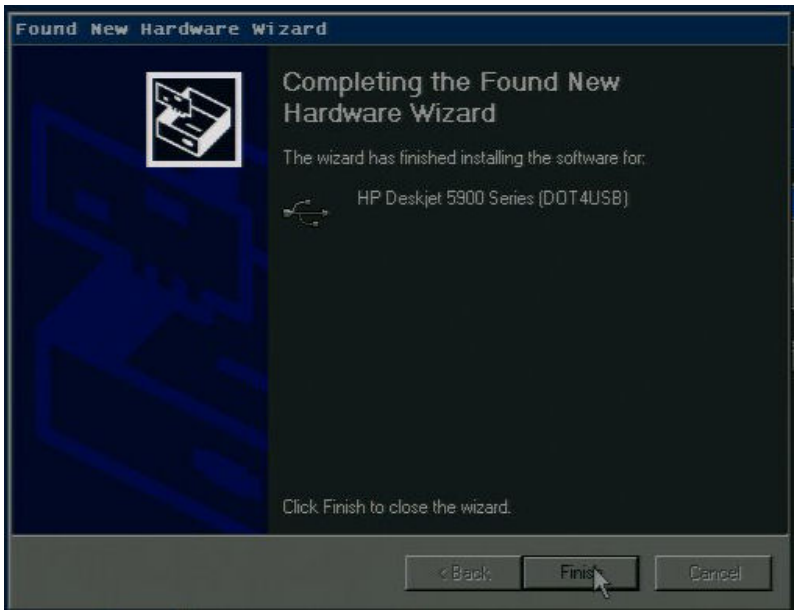
- Select “No, not this time” and click next. The following screen will pop up.


Found New Hardware Wizard
This wizard helps you install software for:
Deskjet 5900 series
If your hardware came with an installation CD or floppy disk, insert it now.
What do you want the wizard to do?
Install the software automatically (Recommended)
Install from a list or specific location (Advanced)
Click Next to continue.
< Back
Next >
Cancel

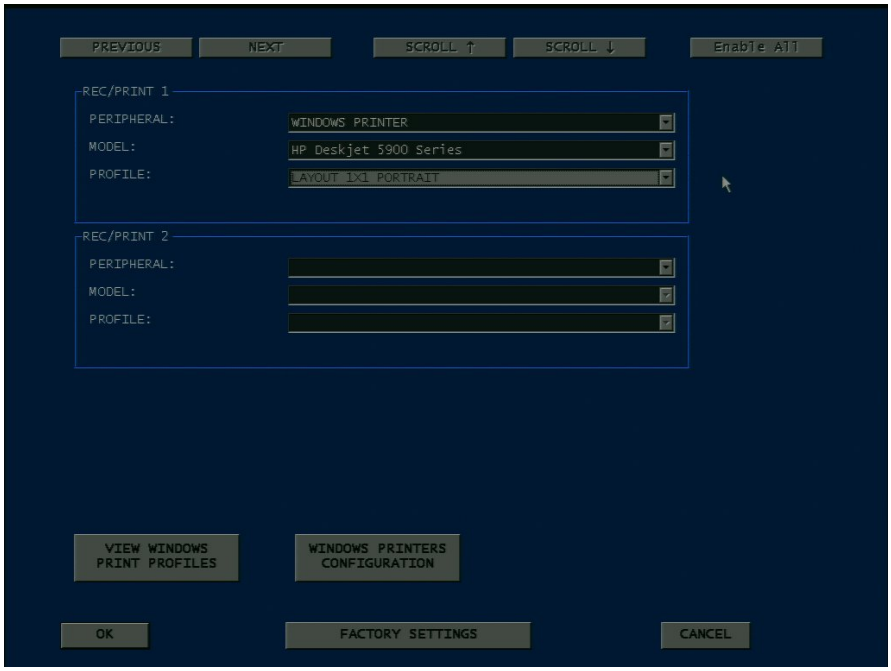
- Select “Install from a list or a specific location” and click next. The following screen will pop up.


Found New Hardware Wizard
Please choose your search and installation options.
Search for the best driver in these locations.
Use the check boxes below to limit or expand the default search, which includes local paths and removable media. The best driver found will be installed.
Search removable media (floppy, CD-ROM...)
Include this location in the search:
F:\drivers_hp_5940\temp
Browse
Don't search. I will choose the driver to install.
Choose this option to select the device driver from a list. Windows does not guarantee that the driver you choose will be the best match for your hardware.
< Back
Next >
Cancel

- Select “Include this location in search” and specify the path were the printer driver resides or insert the driver CD and select “search removable media”. Install the printer drivers only because all other printer related software could interfere with the MyLab software. Click next. The following screen will pop up.


Found New Hardware Wizard
Completing the Found New Hardware Wizard
The wizard has finished installing the software for:
HP Deskjet 5900 Series (DOT4USB)
Click Finish to close the wizard.
< Back
Finish
Cancel

- Click “Finish” to complete the printer driver installation and return to the “Peripherals screen”.



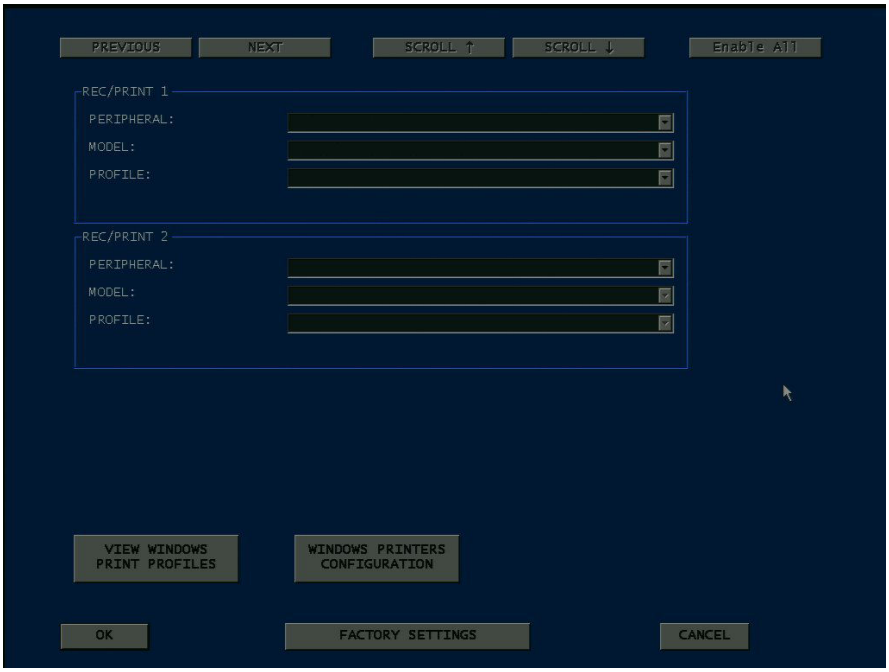
- Select “Windows printer” and the model of the printer in the peripherals menu. Set a print profile and click “ok”.
- In the figure above the network printer will be available under button.

1

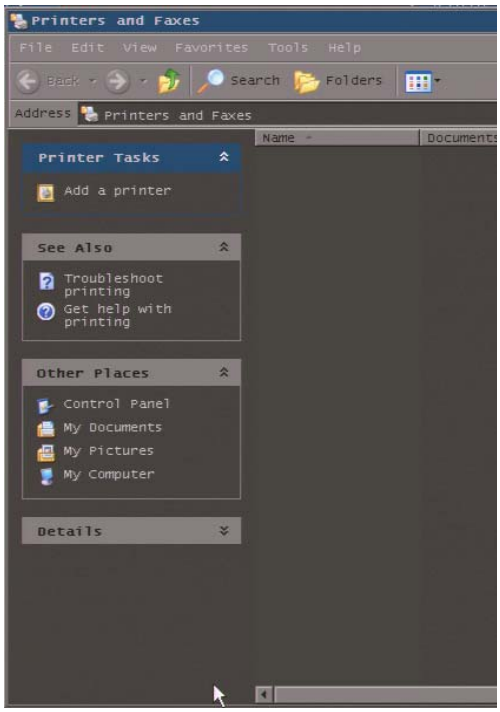
6.16 Network printer installation.

Assumed that the Network Configuration is set as described in section 6.10 on page 47 this is the procedure to install a network printer. (i.e. the Service key is not required.).

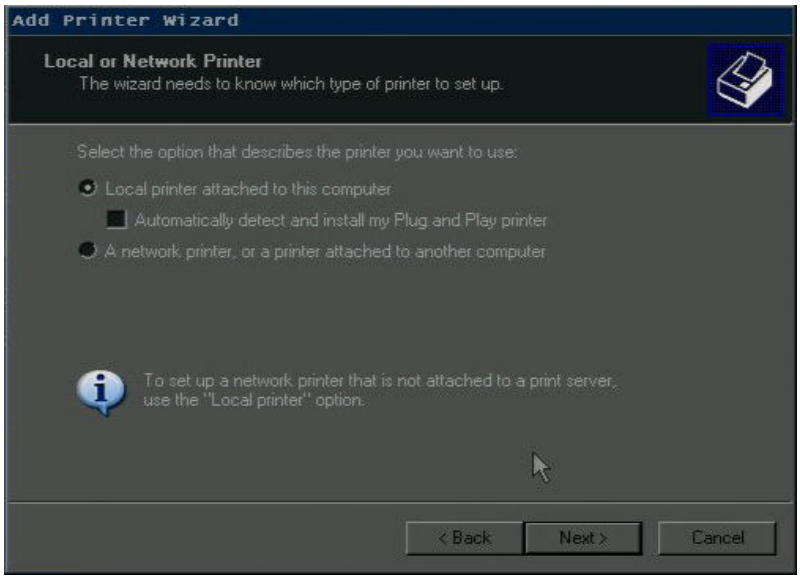
- Pres the MENU key.
- Select the “peripherals” option.
- The system displays the following menu.



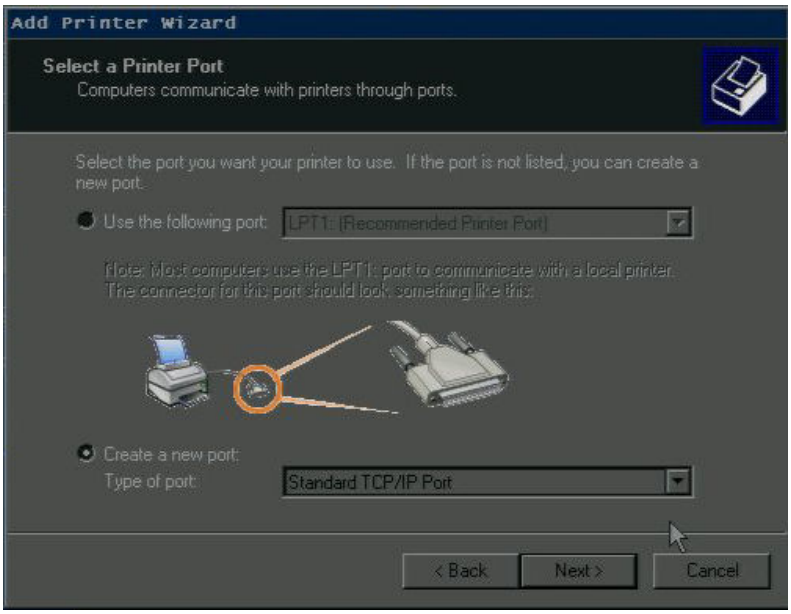
- Select the “windows printers configuration” option.



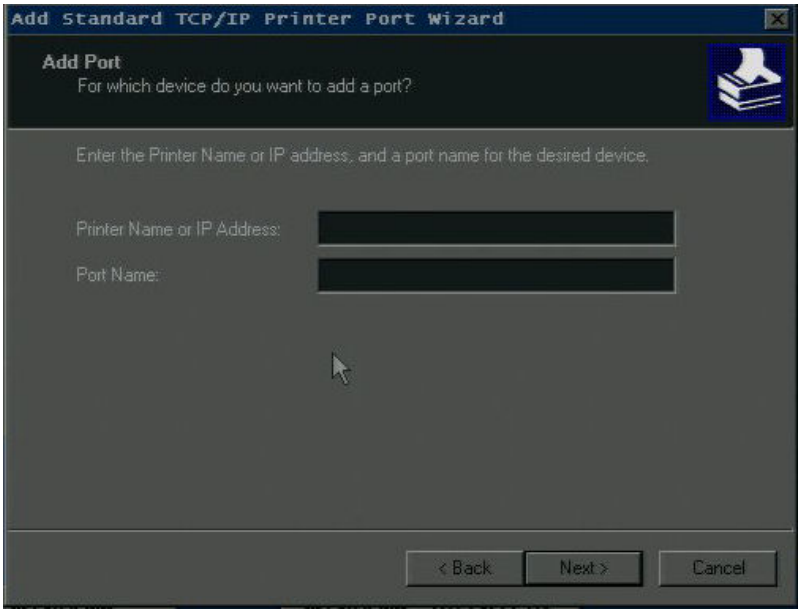
- Select “Add printer”.


Add Printer Wizard
Local or Network Printer
The wizard needs to know which type of printer to set up.
Select the option that describes the printer you want to use:
Local printer attached to this computer
Automatically detect and install my Plug and Play printer
A network printer, or a printer attached to another computer
To set up a network printer that is not attached to a print server, use the "Local printer" option.
< Back
Next >
Cancel

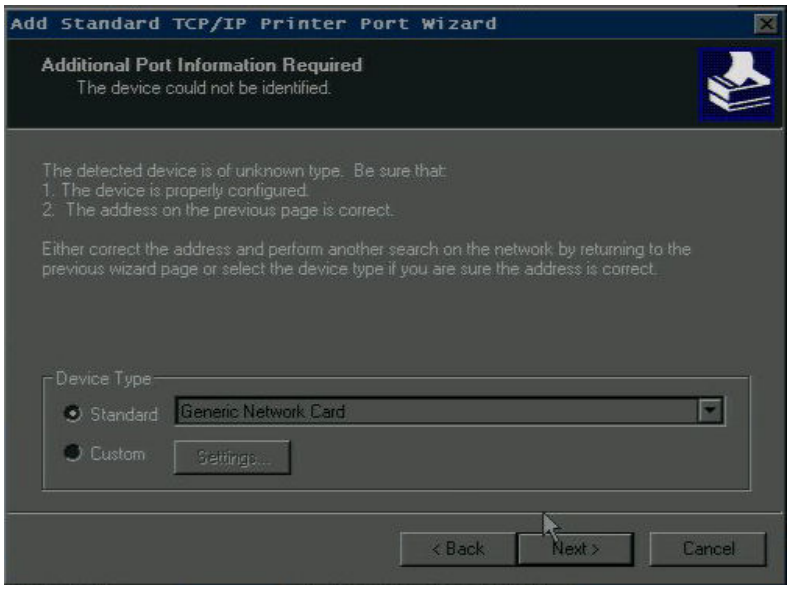
- Select “Local printer” and select “Next”.


Add Printer Wizard
Select a Printer Port
Computers communicate with printers through ports.
Select the port you want your printer to use. If the port is not listed, you can create a new port.
Use the following port:
LPT1: (Recommended Printer Port)
Note: Most computers use the LPT1: port to communicate with a local printer. The connector for this port should look something like this:
Create a new port:
Type of port:
Standard TCP/IP Port
< Back
Next >
Cancel

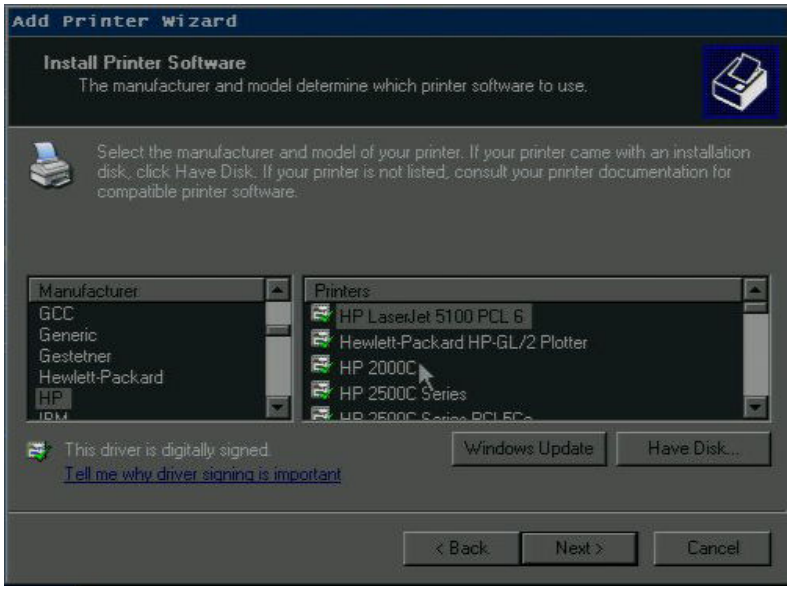
- Select “create a new port” and make the selection “Standard TCP/IP Port”. Then select “Next”.


Add Standard TCP/IP Printer Port Wizard
Add Port
For which device do you want to add a port?
Enter the Printer Name or IP address, and a port name for the desired device.
Printer Name or IP Address:
Port Name:
< Back
Next >
Cancel

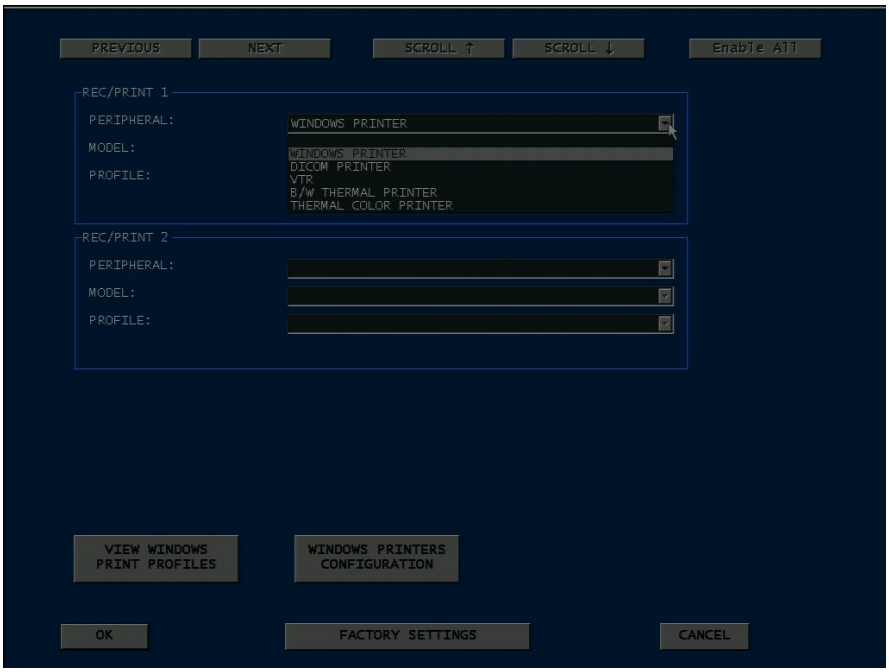
- Enter the IP address of the Network printer and a port name; by default the port name will be the IP address. Then select “Next”.


Add Standard TCP/IP Printer Port Wizard
Additional Port Information Required
The device could not be identified.
The detected device is of unknown type. Be sure that:
1. The device is properly configured.
2. The address on the previous page is correct.
Either correct the address and perform another search on the network by returning to the previous wizard page or select the device type if you are sure the address is correct.
Device Type
Standard
Generic Network Card
Custom
Settings...
< Back
Next >
Cancel

- Select “Generic Network Card” and select “Next”.


Add Printer Wizard
Install Printer Software
The manufacturer and model determine which printer software to use.
Select the manufacturer and model of your printer. If your printer came with an installation disk, click Have Disk. If your printer is not listed, consult your printer documentation for compatible printer software.
Manufacturer
GCC
Generic
Gestetner
Hewlett-Packard
HP
Printers
HP LaserJet 5100 PCL 6
Hewlett-Packard HP-GL/2 Plotter
HP 2000C
HP 2500C Series
This driver is digitally signed.
Tell me why driver signing is important
Windows Update
Have Disk...
< Back
Next >
Cancel

- Select “Have disk”.
- Browse the installation CD and select only the Windows XP printer driver. It is recommended to install printer drivers only. Additional printer applications may interfere with scanner operation.
- Then select “Next”.
- Finish the “add printer wizard” and return to the peripherals menu.



- Select “Windows printer” and the model of the printer in the peripherals menu. Set a print profile and click “ok”.
- In the figure above the network printer will be available under button.

1

6.17 Anti virus protection

Antivirus Protection on MyLab Systems
As every other computer system, MyLab units can be exposed to malware attacks. The term malware indicates a software (sometimes called virus, trojan horse, worm, etc.) designed to infiltrate or damage a computer system without the owner knowing. Theoretically, malware can affect the operations of a computer system in many ways: it could delete its system files but it could also compromise the security of the machine, allowing unwanted exposition of the data contained in it. In a medical imaging system, this could compromise the privacy of the examined patients or damage the exam database.
Esaote develops its products with the objective of providing our customers with enhanced security capabilities and is committed to cooperate with customers in their efforts to comply with security and privacy laws and regulations (HIPAA in the U.S.A., EU Security Directive in Europe …).
Unfortunately, as for any other computer system, internal security measures do not ensure a complete protection of the system against malware. For this reason the service technician must be aware of these internal measures and know which is the best approach to work with a MyLab system in the best possible security conditions.

Malware Infection
Malware can enter into a computer system when executing a program with a viral payload. Such a program could be either intentionally or accidentally executed. Normally, a MyLab system does not allow to intentionally execute other software

programs than the pre-loaded ones: exceptions occur when applying a software upgrade coming from Esaote or when installing a printer.
Esaote manufacturing plants and R&D departments follow a strict corporate antivirus policy:

- Every computer is continuously updated with the Operating System patches.
- Every computer runs continuously updated anti-virus software and the internal network is protected through firewalls.
- All the software coming from Esaote is released on read-only DVDs-R, burnt on systems carefully protected against viruses.

NOTE
Esaote does not authorize any operation different from the ones described in the Operator manual and in the Service manual. Any system malfunctioning caused by unauthorized operations is considered as falling under the user's or the technician's responsibility.

Operating System Patches Policy
Malware can also enter a computer system through the data network, exploiting a failure of the Operating System. For this reason, it is very important to install as soon as possible the relevant security patches released from the Operating System manufacturer.
Esaote will include the Operating System patches into the MyLab system software releases: this will ensure that the patches do not affect the system and are validated by Esaote.
At least every six-eight months, Esaote will issue a new software release, including all relevant patches released by Microsoft.

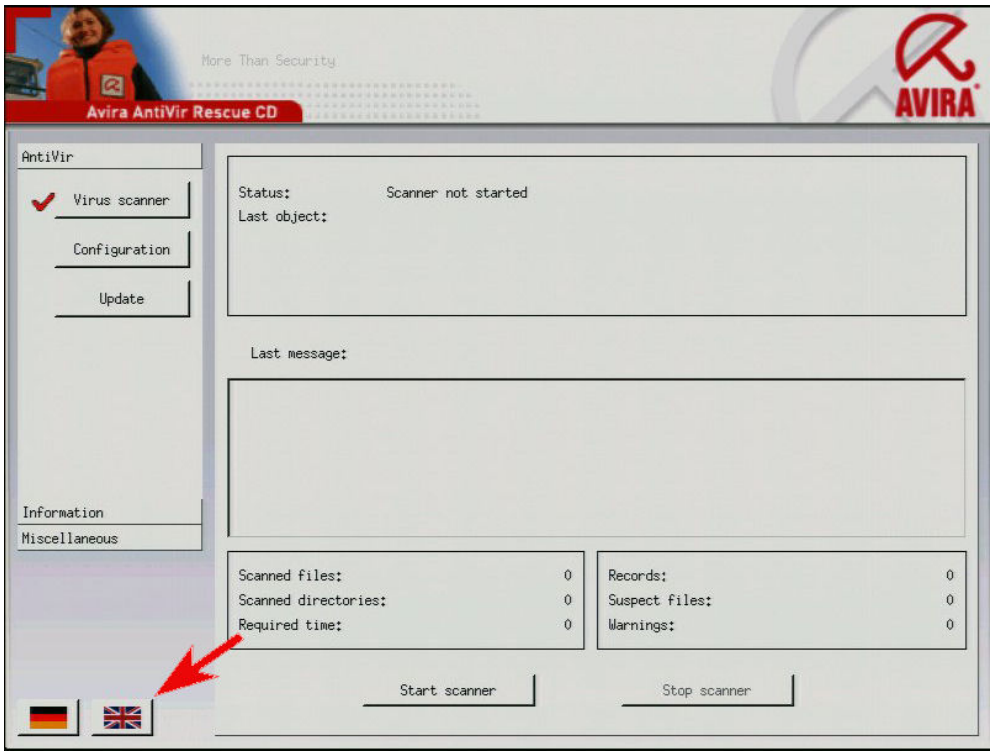
Antivirus
Esaote does not install an anti-virus program because it could affect the regular operations of the system: to be really effective, antivirus software should be configured in a way that heavily limits the system resources, especially regarding the real-time ultrasound acquisition. Moreover any antivirus software is only effective if continuously updated (daily basis). As explained above, any update should be carefully validated by Esaote, to be sure it does not affect the regular operations of the machine.

In case of serious doubts, it is possible to run an external antivirus program, with the sole purpose of reporting if the MyLab system has been really attacked by a virus, without changing its files in any way. We suggest using the Avira Antivir Rescue System. It is a free product that allows you to burn a bootable CD-R that can be used to scan the MyLab system.

To use the most recent Avira Antivir Rescue System CD-R please follow this procedure.

1. You need a Windows XP / Vista computer which is carefully managed and is applying the latest security patches, running a correctly updated antivirus and protected with a suitable firewall. This computer needs a CD-ROM burner and a connection to the Internet.

2. Access the web page: http://www.free-av.de/en/tools/12/avira_antivir_rescue_system.html (or search on the Avira web site the Antivir Rescue System download page) and download the product (exe file).
3. Insert a write-only CD-R into your CD-R burner and run the downloaded exe file. It will burn a CD-R with the latest version of Avira Antivir Rescue System.
4. Disconnect the MyLab system from the data network.
5. Connect a usb mouse to the system because the trackball will not work.
6. Switch to the Windows environment to see the antivirus running:
   a. Turn the unit on, insert the Avira CD-R and turn the unit off.
   b. Turn the unit on. Wait until the unit start up procedure is over, until the system displays the Real Time image with the HD icon grey.
   c. Press Ctrl + Alt + ARCHIVEREV to display the antivirus screen.
7. The following screen should appear:



8. Click on the British flag on the lower left to enable the English language:
9. By default, the Avira Antivir Rescue System is configured to examine all the files on the unit, producing a report without changing anything. Please do not change these settings, and just press “Start scanner”.
10. Scanning the whole unit could take from a few minutes to many hours, according to the size of the image database. If the Avira Antivir Rescue System reports any suspect file:
    a. Reboot the machine, remove the Avira Antivir Rescue System CD and execute a complete backup of the system (archive, settings, etc.).
    b. Completely re-install the system software and BIOS using a BIOS CD and an update DVD with the latest available MyLab software release The update files are available on the helpdesk FTP site (ftp://gatekeeper2.pie.nl). For more info see the Technical note regarding a software update, which is available on the protected web.

c. Please note that reconnecting the MyLab to the data network before sanitizing it could allow a new malware attack.

Firewall

It is anyway advisable to close any possible access from the data network: for this reason all unused network ports are closed in the MyLab system.
To minimize the exposition to the threats coming from the network, medical devices based on a networked computer system, like the MyLab system, should be connected only to a carefully managed data network, i.e. a network that is carefully isolated from external networks through suitable firewalls and that is not used to connect external devices (such as laptops coming from outside the department, etc.). See for example, the USA Department of Veterans Affairs Medical Device Isolation Architecture Guide, available at the HIMSS website: http://www.himss.org/ASP/topics_FocusDynamic.asp?faid=101.
To ensure a complete protection of the MyLab system from any network attack, Esaote suggests to use a complete agent less intrusion-prevention system: this is a system that acts like a firewall protecting the network against malware from outside, but also checks the internal network traffic, without require any additional software installation in the MyLab system (see for example Trend Micro Network VirusWall Enforcer or Firebox X Core Unified Threat Management products or SonicWALL TZ products, or similar).

NOTE
It is suggested to contact the network administrator to know the network policy.

Enabling the Internal Firewall

If the data network cannot be correctly isolated from external threats, another possible solution to suggest to the customers is to enable Windows XP internal firewall and configure it to close all incoming network ports. This solution is **less secure** than using a protected data network with external firewalls and has some disadvantages: **it won't be possible anymore to send data to a Network Directory nor to use the DICOM Storage Commitment**.
This is the procedure to activate the internal firewall in windows XP:

- Turn the system on with the service key inserted.
- Press the ARCHIVE REV key.
- Press Ctrl + Esc keys to display the Windows menu.
- Select "Settings" and "Control Panel".
- Select "Windows Firewall".
- The system may require to start the Windows Firewall/Internet Connection Sharing (ICS) service. Select "Yes" and press ENTER
- In the Windows Firewall menu - "General" tab, enable both the "On (recommended)" and "Don't allow exception" fields.
- Confirm the selection by pressing OK and turn the system off.
- Remove the service key.

Security Access Control and Auditing

The MyLab system has a complete and configurable security access control process. When enabled, users have to provide a login and a password to access the unit. For

the description of the Security settings see the “Advanced Operations” manual, section “System Configuration”, chapter “Security”. This process can be tailored to fulfill the local laws and regulations.
When enabled, this process will also produce a log file that traces every access to the machine (access log), allowing the System Administrator to fulfill the security regulations required by this kind of logging. This log file can be considered to have adequate characteristics of completeness, inalterability and integrity. This log file, called *UserManagement_0.txt*, will be automatically produced by the system, which archives it internally.
This file can be exported on a USB pen drive: the log file can be then considered complete. The MyLab system can be considered a closed system: the normal user (including the System Administrator) cannot modify the contents of this log file, this guarantees its inalterability. Moreover it is always possible to export the log file to verify its integrity.

6.18 Log Files

The Log and Shut Down files are useful tools and therefore should be sent to the helpdesk in case of a problem.
The log files have to be saved soon after the problem occurs or, the latest, at the next start up. The files have a FIFO structure with a limited memory availability: when the log file memory is full, the oldest events registered in the files are eliminated to free space for the recent ones. For this reason the log files have to be saved as soon as possible. For detailed information on how to save the log files see section 6.9.1.

Log Files Organization
The log files are organized in following twelve folders:

- ApiTemp
- Dam
- DamOrganizer
- Dinamo
- MediaExport
- MediaRec
- PrintDispatcher
- Setup
- Star
- StarTemp
- Upgrade
- UserManagment

ApiTemp and StarTemp Folders
The files contained in these folders trace the main Windows operations, such as the operation done in Exam review (TempArchiveLog_0.txt) and in Archive review (MainArchiveLog_0.txt).

Dam Folder
The Dam folder traces the communication between the processors installed in the unit. The folder contains the following files and folders:

- *Dam Service_0.txt*, that traces the communication protocol between the processors. The system model and S/N, the installed software, the installed licences are logged in this file
- *Dam Service.bck*, that contains the information on the far operations
- *DamShutDown_0.txt*, that traces the unit shut downs.
- *DamPrintFiles*, folder, which contains temporary files for printing operations.
- *DamTargetFiles*, folder, which contains temporary files for saved clips/images of the current exam.
- *Panoramic*, folder, which contains temporary files for saved Panoramic (VPan tool) images of the current exam.
- *ThreeD*, folder, that contains temporary files for saved 3D/4D clips/images of the current exam.

Data Organizer Folder
The Dam folder traces the exam copy process.
The folder contains the following files:

- *DataOrganizer Service_0.txt*, where the process operations are traced. Each copy operation is identified by an UID number. Any error, when present, after a certain UID number can indicate which copy fails.
- *DataOrganizerQueue.xml* , where the queue of the copy operations is traced.

Dinamo Folder
The Dinamo folder traces the DICOM conversion process of the exams. The folder contains:

- *Dinamo-Dicom Service_0.txt*, file where the failed operations are traced. Each Dicom operation is identified by an UID number. Any error, when present, after a certain UID number can indicate which operation fails.
- *QueueSerial.xml*, file where the Dicom operations are queued
- *Log* folder, that traces the used Dicom libraries.

SetUp Folder
This folder logs the setups of a software upgrade.

ThreeDLogs
The folder traces the main operations done in the 3D/4D environment.

Upgrade Folder
This folder logs the processes that automatically run at the first start up after an upgrade.

MediaExport Folder
This folder traces the AVI/BMP/JPEG/PNG conversion process (during the **EXPORT** option and the “Export” option at the end of the exam). The folder contains the following files:

- *MediaExport Service_0.txt*, where the process operations are traced. Each export operation is identified by an UID number. Any error, when present, after a certain UID number can indicate which operation fails.
- *MediaExportQueue.xml*, where the queue of the export operations is traced.

Media Rec Folder
This folder traces the burning process. The folder contains the following files:

- *MediaRec Service_0.txt*, where the burning process operations are traced. Each burning operation is identified by an UID number. Any error, when present, after a certain UID number can indicate which operation fails.
- *MediaRecQueue.xml* , where the queue of the burning operations is traced (“Operations” option of the media menu).

Print Dispatcher Folder
This folder traces the printing process. The folder contains the *PrintDispatcher Service_0.txt* file, where the various operations of the printing process are traced. Each printing operation is identified by an UID number. Any error, when present, after a certain UID number can indicate which operation fails.

User Management Folder
This folder traces the management of the users. All the logins done with the service key are traced in the *UserManagement_0.txt* .

7 Safety test

Every MyLab 40 unit complies with EN60601-1 (IEC 60601-1) standard. The MyLab 40 is Class I Type B and BF (Ultrasound probe).

We strongly recommend performing Safety Tests every time new peripherals are powered through the unit or that the unit is opened to perform service.
It is recommended to perform the safety tests every two years. If the system is used in the Intensive or Coronary Care, it is recommended to perform the safety tests once a year.
Local directives may be different but are mandatory to comply to.

WARNING
If the measured values exceed the reference values, indicated in the following table, don't use the unit. Contact the manufacturer.

The parameters to be tested are the following:
- Impedance of Protective Earth Connection
- Earth Leakage Current
- Enclosure Leakage Current
- Patient Leakage Current
- Patient Auxiliary Current

This chapter defines safety Parameters and their range according to EN60601-1 standard and describes the safety tests to be carried out on the equipment.

Definitions

1) Impedance of Protective Earth Connection
The impedance between the Protective Earth (PE) terminal of the mains input connector and any accessible metal part.

2) Earth Leakage Current
The current that flows from the mains terminals (P=Phase, N=Neutral) to the Protective Earth (PE) through the insulation.

3) Enclosure Leakage Current
The current that flows between the enclosure and the Protective Earth (PE) terminal.

4) Patient Leakage Current
The current that flows through the applied parts (ECG and US probe) towards the Protective Earth (PE).

5) Patient Auxiliary Current
The current that flows between two different applied parts (for instance between two ECG electrodes).

The table below provides the user with a list of the parameters to be checked, the maximum values and references to the IEC 60601-1 standard (1988), II Edition.

Parameter	Max Value N.C.	Max Value S.F.C.	EN 60601-1
Impedance of protective earth connection (with Mains Power cable)	0.2 Ω	-	18.f
Earth leakage current	0.5 mA	1 mA	19.4.f
Enclosure leakage current	0.1 mA	0.5 mA	19.4.g
Patient leakage current	CF 0.01 mA ac B/BF 0.1 mA ac	CF 0.05 mA ac B/BF 0.5 mA ac	19.4.h
Patient leakage current (mains on applied part)	-	CF 0.05 mA BF 0.5 mA	19.4 h
Patient auxiliary current	CF 0.01 mA B/BF 0.1 mA	CF 0.05mA B/BF 0.5 mA	19.4.j

N.C. Normal Condition
S.F.C. Single Fault Condition

7.1 Safety test, unit

Requisites:

- Earth leakage tester, such as BIOTEK 01 Pro.
- Metal foil, maximum size 20 x 20 cm.

NOTE
The test must be carried out by skilled personnel using equipment compliant with the reference standard indicated. ESAOTE recommends the use of the automatic BIO-TEK 601-PRO equipment manufactured by BIO-TEK Instruments INC. or equivalent equipment.

- Power the automatic testing equipment through mains supply and the equipment under test through the automatic equipment.
- Set the automatic equipment according to its user manual in order to perform a Class I, Type CF equipment test.

Measurement of the Impedance of Protective Earth connection

- Connect the test lead to unit equipotential node.
- Activate the procedure for measuring the Impedance of Protective Earth on the automatic equipment.
- Check that the value indicated complies with the indications given in the reference table for normal condition (NC).

If the measured value is higher than the value in the table, do not use the equipment and contact the manufacturer.

Measurement of Earth leakage current

- Activate the procedure for measuring the earth leakage current on the automatic equipment:
    1. Check that the value indicated complies with the indications given in the reference table for normal condition (NC).
    2. Repeat the procedure simulating a break in a power conductor, by means of the automatic equipment, and check that the value indicated complies with the indications given in the reference table for the single fault condition (SFC).
- Repeat the above measurement procedures inverting the polarity of the power conductors, by means of the automatic equipment

If any measured value is higher than the value in the table, do not use the equipment and replace the power cable. Repeat the procedure with the new cable and if the values continue to be higher, contact the manufacturer.

Measurement the Enclosure Leakage Current

- Connect the test lead to the metal foil.
    1. Place the metal foil in close contact with the unit and activate the procedure for measuring the enclosure leakage current on the automatic equipment; varying the foil position, check that the value indicated complies with the indications given in the reference table for the normal condition (NC)
    2. Repeat the procedure simulating a break in the earth wire, by means of the automatic equipment, and check that the value indicated complies with the indications given in the reference table for the single fault condition (SFC).
    3. Repeat the procedure simulating a break in a power conductor, by means of the automatic equipment, and check that the value indicated complies with the indications given in the reference table for the single fault condition (SFC).
- Repeat the above measurement procedures inverting the polarity of the power conductors, by means of the automatic equipment.

If any of the measured values are higher than the value in the table, do not use the equipment and contact the manufacturer.

7.2 Safety test, probe

For any probe in use with the unit, repeat the procedure for measuring the Patient Leakage Current test (without application of mains voltage on applied part), immerse the probe in a saline solution connecting the test lead to a metal plate in the solution. (Saline = 1000gr water + 50gr salt).

Please refer to the Transducers and Consumables manual for maximum immerse depth of the probes . This manual can be found on the user manual CD.
The document numbers are as follows:

English	21B04ENxx
German	21B04DUxx
French	21B04FRxx
Spanish	21B04SPxx
Italian	21B04ITxx

The test must be performed in any Real Time mode application. The probe must be connected to the unit

- Activate the procedure for measuring the Patient leakage current on the automatic equipment and check that the value indicated complies with the indications given in the reference table for the normal condition (NC).
- Repeat the procedure simulating a break in the earth wire, by means of the automatic equipment, and check that the value indicated complies with the indications given in the reference table for the single fault condition (SFC).
- Repeat the procedure simulating a break in a power conductor, by means of the automatic equipment, and check that the value indicated complies with the indications given in the reference table for the single fault condition (SFC).

Repeat the above measurement procedures inverting the polarity of the power conductors, by means of the automatic equipment.

If any of the measured values are higher than the value in the table, do not use the probe and contact the manufacturer.

WARNING
Any break in the probe case or in the probe cable can cause an electrical hazard.
Do not use the probe and contact the manufacturer.

8 ESD

8.1.1 What is ESD

Electro Static Discharge (ESD) is the transmission of electro static charges between two bodies with a potential difference.
This transmission can be achieved by direct contact or by an inducted electro static field.

Electro static discharges are not always noticed by men, because ESD is:

- sensed at 3.500 Volt
- audible at 4.500 Volt
- visible at 5.000 Volt

Components and integrated circuits are more sensitive as men and might be damaged by lower voltage discharges.

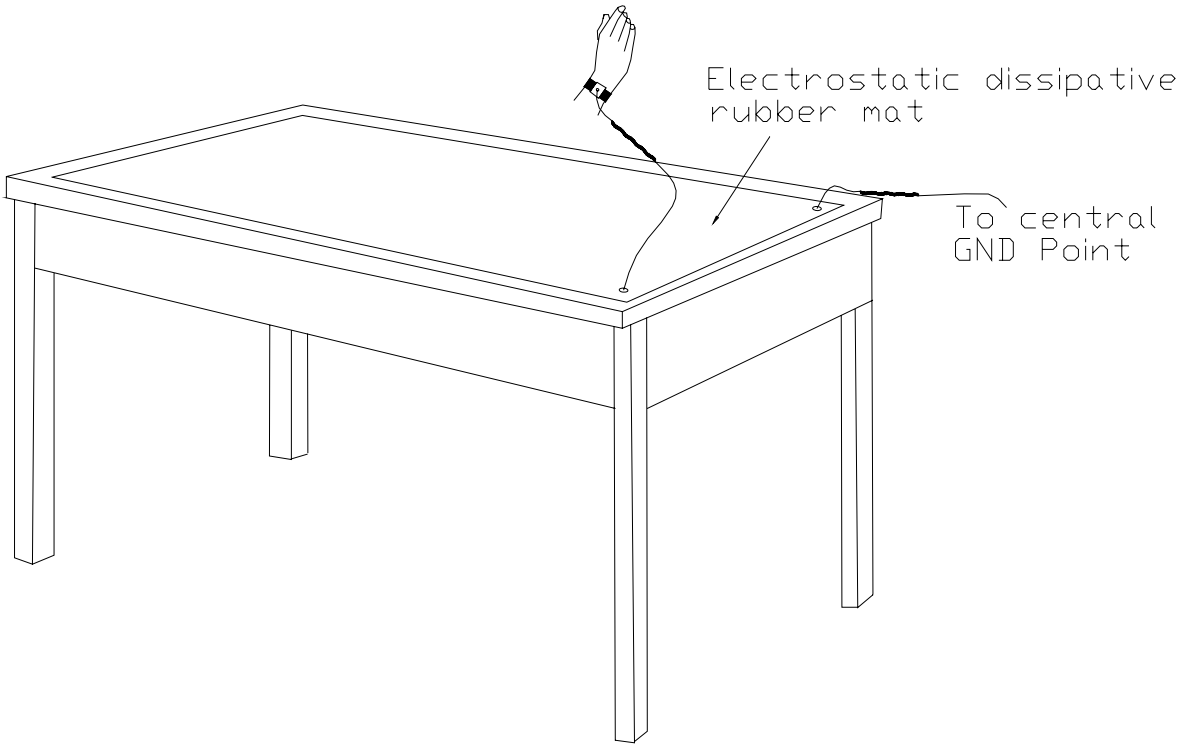
component type	ESD sensitivity in Volts
V-MOS	30-1800
mosFET	100-200
EPROM	100
JFET	140-7000
OP-AMP	190-2500
C-MOS	250-3000
Schottky Diodes	300-2000
Bipolar Transistors	380-7000
ECL	500-1500
SCR	680-1000
Schottky TTL	1000-2500

8.1.2 Preventing ESD damage

- Use electro static sensitive parts only in an ESD safe workshop.
- Use ESD safe packing material.
- Remove all static chargeable materials (plastics) from the workshop.
- Wear ESD safe clothing.
- Always check wrist strap and other ESD equipment before use.
- Be grounded.
- BE AWARE.

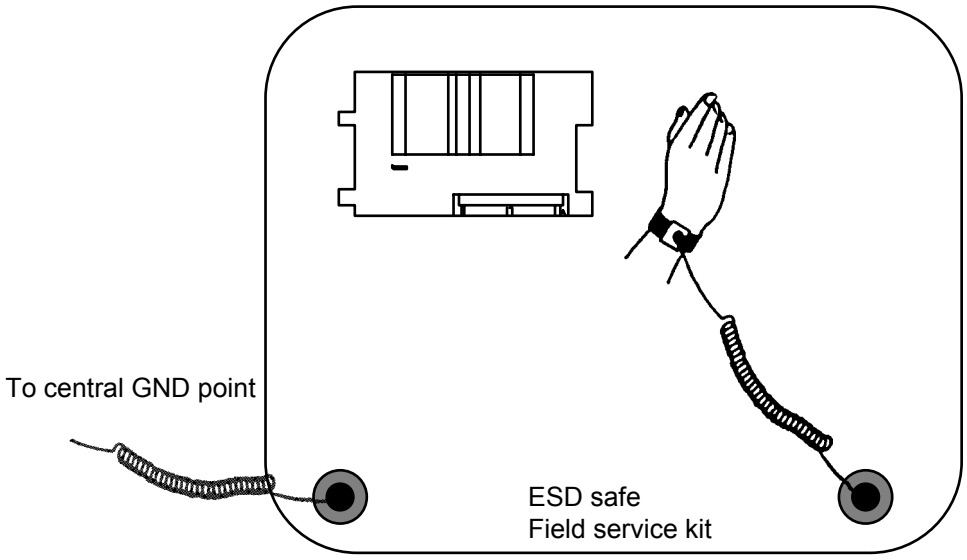
8.1.3 ESD save workshop

To be sure that there is no potential difference between body, boards and work surface, the work surface should be made of electrostatic dissipative rubber.
The work surface should be connected to a central ground point.
The engineer, handling the boards should also be connected to the central ground point, either through wrist strap or heal strap (and conductive floor).



8.1.4 ESD safe field service

To enable ESD field safe service an ESD field service kit has to be used when handling boards.
This ESD field service kit should be connected to a central ground point and the service engineer should be connected to the ESD field service kit through a wrist strap.
Handle boards only on this ESD field service kit and pack in ESD safe packing material.



8.1.5 More information about ESD precautions.

All precautions against ESD damage are described in the CECC 00015/I regulations, composed by the CECC (Cenelec electronic Components Committee).